
Foodborne illnesses Reduction Strategy Review

A Report for the NSW
Food Authority, May 2016

Project No. RFQ-DI-DPI-15-753

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Disclaimer

This report was prepared for the New South Wales Food Authority at their request.

The report is based on discussion with Mr Bruce Nelan of the NSW Food Authority, documents provided by Mr Nelan, relevant refereed scientific papers and reviews from the published literature, and relevant reports from government, industry and standard setting agencies.

The author has assumed that:

the scientific papers used as sources of information accurately represent the findings of the research carried out under the conditions described in the papers;

the scientific reviews, government and industry reports used as sources of information accurately reflect the state of knowledge at the date of their publication.

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Executive summary

The Project

The New South Wales Government has developed a visionary plan for the food industry, *NSW Food Safety Strategy 2015 – 2021*. Achievement of the strategy's goal includes reducing the number of foodborne illnesses in NSW by 30% and delivering safe superior-quality food to local and international consumers. A related project was developed by the NSW Food Authority (NSW FA) to better understand foodborne illnesses and reduction strategies developed and adopted by different countries, and to identify any gaps between international strategies and current strategies applied in NSW. The focus was on 3 target microorganisms, *Salmonella*, *Listeria monocytogenes*, and *Campylobacter*, and food allergen induced anaphylaxis, that are considered to be the most important causes of foodborne illnesses in NSW. This project addressed the 3 targeted microorganisms. The project objectives were to:

1. Summarise key aspects of risk reduction strategies for non-typhoid *Salmonella* (NTS), *L. monocytogenes*, and *Campylobacter* when transmitted by food and spanning the farm to plate continuum in the United States of America (USA), New Zealand (NZ) and the United Kingdom (UK).
2. Summarise the approach of the Codex Alimentarius Commission (CAC) Food Hygiene Committee (CCFH) to food safety risk management relevant to these pathogens as this is the reference for international trade and underpins the approach in these countries and Australia as member countries.
3. Identify new technologies and tools that could be used by risk managers in industry and government to strengthen risk reduction strategies for the specified 3 pathogens.
4. Assess the success of the respective country risk reduction strategies summarised where such information is available.
5. Conduct an assessment of the current approaches in NSW that may impact on the level of foodborne risk from the 3 identified pathogens and identify significant gaps between NSW and international approaches where they exist.

This project was undertaken as a desktop study drawing on the knowledge and experience of the Contractor, and information available via internet sources such as those of the respective governments and international agencies, industry and related websites, internet news sites, the published scientific literature, and personal contacts.

Strategic approaches in the USA, UK and NZ

Food safety management within the CCFH and the reviewed countries have had a common evolution over the last few decades beginning with hazard control programs supported by basic sanitation and hygiene procedures and these continue to provide the foundation for food safety management. This approach successfully brought some microbial foodborne illnesses under control; however, it has been less successful for control of certain foodborne zoonoses and listeriosis. Commodity specific strategies addressing a range of hazards were developed with varying levels of success. Subsequently more targeted pathogen specific strategies for prioritised foods or consumers are being used. At the same time, their risk managers have further shifted to risk- and evidence-based approaches targeting risk management options through chain that have the greatest impact on reducing final health risk. Their risk managers are applying improved pathogen analysis and typing tools, making use of food safety metrics, and data from enhanced epidemiological surveillance and food attribution studies. They are taking a common approach with governments setting national goals for the respective

foodborne illnesses and their agencies responding by developing the pathogen/food specific strategies to meet the goals while maintaining basic hazard and hygiene regulations. The agencies follow a systematic process or a risk management framework with preliminary activities prioritising food groups by risk, estimating their contribution to the health goals and selecting effective risk reduction measures, followed by implementation, monitoring and review. The expectation of performance from risk reduction measures at points along the chain are articulated as performance targets that have to be met by food chain participants to collectively achieve the health goals.

This approach, in particular the use of performance standards (PSs) or targets, appears to be the most important regulatory process in driving success of pathogen reduction strategies as opposed to the beneficial effects of individual interventions. For example, performance targets for poultry processing enforced in NZ are considered the most important measure in the success of their *Campylobacter* strategy and the UK has a similar approach; PSs have impacted on NTS control in eggs and chicken in the UK and the European Union (EU); and, in the USA PSs drive control of *Listeria* in ready-to-eat (RTE) foods and pathogens in fresh meat and poultry. Within this system industry may choose the interventions they implement, some may be mandatory; however, there is a mandatory requirement to meet the defined targets. The performance targets are guides for industry, are used in regulatory oversight, strategy review, and as measures of progress.

Success and progress in meeting the performance targets result from a combination of intervention measures applied through chain, some regulatory, and some voluntary and industry initiated. The controls for the zoonotic pathogens present different challenges to that for an environmental organism. Pathogen targeted approaches have been successful, however, they also rely on continuing improvement of general food safety and hygiene-based measures. The levels and the speeds of achieving success have been influenced by various and differing external drivers such as the nature and complexity of the food supply and local culture, commitment of the government and food chain participants, cost, and political and consumer constraints.

The 3 bacterial pathogens are among those of key concern for the countries reviewed; however, they are addressed with competing priorities e.g. foodborne viral infections and Shiga toxinogenic *Escherichia coli* (STEC), and the priority ranking among them differs. *Campylobacteriosis* is a priority concern in the UK and NZ and has been of lesser importance in the USA that has had a much lower incidence. *Salmonellosis* is most important in the USA and the UK, and the USA has experienced epidemics of *S. Enteritidis* infections. *Listeriosis* is important in all countries due to the severity and high mortality. The food groups of most importance vary although some are common e.g. NTS and egg and egg based dishes, *Campylobacter* and chicken meat and *L. monocytogenes* in chilled RTE foods supporting its growth. The priority of foods of concern is dynamic, foods come under control giving others prominence, and some new foods or foods from changing production/processing systems or preference have emerged. In the USA, *Campylobacter* is more important in dairy products than chicken meat although only in specific exposed community groups, NTS and *L. monocytogenes* have emerged as more important pathogens in fresh produce than meat and dairy foods. Red meat is only of concern with particular products e.g. minced or non-intact cuts, while pork is of increasing concern in the EU and USA. The intervention measures permitted in countries influence the choice of risk management options and this has had some influence on the speed of progress.

Salmonellosis

Meeting health targets for salmonellosis appears the most challenging due to the diversity and ongoing changes of foodborne transmission pathways, the multitude of risk factors and the dynamics among NTS types that are a moving target. *Salmonella* strategies in the USA and UK have been strongly

influenced by earlier *S. Enteritidis* (SE) epidemics, the main food vehicle, eggs, and the characteristics of that serotype; however, as the SE epidemics have waned other NTS types and attributed foods have emerged. The USA has identified a wide range of food pathways to be addressed, while NZ's strategy is broad due to lack of attribution data and they are investing in filling this knowledge gap.

In the UK and USA SE epidemics, poultry were the reservoir host; eggs were the main vehicle targeted with lesser focus on chicken meat. CCFH and both countries used quantitative risk assessments and scientific studies to select risk-based interventions with quantifiable outcomes. There has been a common overall approach: prevention of shell egg contamination, prevention of SE growth in eggs after harvest, inactivation of SE in egg products, and food handler/consumer education. Also common, has been the setting of quantitative performance measures for incoming stock, layer flocks during production and shell eggs, and a process criterion for egg product pasteurisation, with corrective actions to prevent contaminated eggs and products entering the marketplace. Each country's focus differs due to their regulatory limitations on allowable intervention measures. In the UK/EU control measures begin at the top of the poultry production pyramid, mandatory maximum national flock prevalence levels are set by the EU at a maximum of 1%, on farm controls are required including voluntary vaccination (mandated in some EU laws and UK farm assurance schemes), testing programs for SE in flocks at different production stages and for shell eggs are mandated, and positive breeding flocks are slaughtered and eggs from positive layer flocks disposed of or pasteurised. The USA require control measures for eggs that are equivalent to a pasteurisation process resulting in at least a 5 log₁₀ reduction in SE. This could be on farm measures and testing or a validated decontamination process or equivalent measures. On farm measures are similar for both, vaccination and feed treatment are recommended, and a systematic flow of testing is required from environment to flocks to eggs with diversion of flocks or shell eggs at each level if positive. The EU requires Class A shell eggs to be kept dry while in the USA they can be washed using chemical decontamination agents and both countries require temperature and time control of eggs post-harvest. Shell eggs are stamped and the USA requires labelling of shell eggs at retail with safe handling instructions. These measures are complimented with specific requirements in the Food Codes covering food service, with recommendations for use of pasteurised products in catering and restaurants and in foods for vulnerable persons, and with extensive information and education for consumers on the risks of consumption of raw or undercooked eggs. Both countries have had success in the reduction of SE in eggs although this has been greater in the UK. The UK FSA has recently relaxed some advice for pregnant women not to eat raw eggs/egg dishes. The UK gives particular credit to the use of vaccines and industry initiated programs in their success. In the USA, SE has rebound in the 2000s with chicken meat becoming an important food source and an increase in SE has been observed in young broilers.

As SE in poultry has come under control other serotypes have assumed a higher proportion among human and non-human NTS isolates. In the UK the overall NTS prevalence has increased in poultry breeders and layer flocks. The EU regulations for foodborne zoonoses have been redefined to reflect health risk and now specify "regulated" NTS serotypes which are those most common in human salmonellosis e.g. SE and Typhimurium (and variants) for layer flocks and broilers, and for breeders there are additional types, Virchow, Hadar and Infantis. Sweden claims to be virtually NTS-free. Their strategy is to include all NTS serotypes with mandatory slaughter of positive flocks and stamp-out programs on all livestock farms and diversion of positive products. They are revising their approach as it is costly and not contemporary and are considering setting defined targets along the food chain.

STEC have become of equal or greater importance than NTS in red meat. The USA mandate use of at least one validated decontamination treatment during slaughter and the EU now allows use of lactic acid sprays on beef carcasses. The USA uses NTS testing of carcasses as a process criterion and in the

EU additional NTS food safety criteria are applied for NTS in meat to be eaten raw or for minced meat or preparations that might be undercooked. Concerns mainly are for specific products and consumer practices e.g. raw or undercooked products, and minced meat and non-intact meat cuts. Labelling with warnings and safe cooking instructions are required on these latter products. Control of NTS in minced beef, the role of lymph nodes and control measures, are under investigation in the USA. Increased control of NTS in pork is under investigation in the EU and USA and recently CCFH have produced draft guidelines for control. In the UK, attribution of pork in salmonellosis has increased. This may be due to comparative changes with the control of NTS in eggs and poultry as the prevalence in herds and processing is unchanged. The USA is surveying pork production and PSs may follow.

The approaches to control of NTS in chicken meat are not dissimilar to that for eggs with an on farm focus in the UK and multi-hurdles on farm and during processing in the USA. The EU has requirements for not more than 2% broiler flock prevalence and uses regulated serotypes (Enteritidis and Typhimurium) as targets. Broiler flock testing is required within 3 wk. of slaughter. Positive flocks are re-tested and can only be conditionally moved to slaughter. In the UK Food Chain Information is supplied to livestock processors unless stock is inspected on farm. For example, NTS status, although not time off feed, or membership of an assurance scheme, has to be provided prior to slaughter to allow HACCP managers to manage positive lots. NTS prevalence in meat and poultry is low.

In the USA, on farm control measures can include use of vaccines, probiotics and organic acids in feed and if preventive controls are not practiced, testing birds and scheduling of processing is recommended. PSs are applied at livestock slaughter. Poultry products have been those insufficiently compliant and also linked with increasing numbers of salmonellosis cases and a rebound in SE cases. Applying a risk-based approach, the focus has recently changed to include all poultry types and to move from PSs for carcasses to PSs for products post-fabrication to reflect the changing retail supplies and consumer exposure, and to more stringent performance targets and sampling plans. Establishment performance in verification testing may be made publicly available. In categorising performance, detection of serotypes of human importance is considered. These are works-in-progress.

Fresh produce, both local and imported, have become a priority for risk reduction of salmonellosis in the USA. A Produce Safety Rule has been introduced where the whole food chain beginning at the farm will be required to meet science-based minimum standards at optimal points for risk reduction. This recent Regulation will be progressively implemented based on a priority risk categorisation of produce types and progress will be monitored by extensive targeted surveillance testing. Some RTE products e.g. nuts have process criteria of a 4-5 log₁₀ NTS reduction. Requirements for sprouted seeds in the Rule include measures for prevention of seed contamination, in process test and hold programs for pathogens, and environmental testing for *L. monocytogenes*.

NTS in dairy products remain a food safety risk where raw milk and dairy products are consumed. The EU permits the sale of these products and regulations include hygiene based controls and hygiene criteria for raw milk depending on use. Raw milk products must be labelled advising of risks associated with consumption. The presence of NTS in dairy foods appears to be low. NZ has recently allowed raw milk to be sold directly from registered farms or home deliveries under a new regulation that requires hygiene measures, temperature and time controls, performance based testing, and labelling with identification, use-by date, storage conditions and hazard warnings included.

Campylobacteriosis

The UK and NZ have very similar overall strategies for *Campylobacter* focused primarily on chicken meat. Both countries set health goals that are further defined for priority foods and articulated as performance targets to guide industry and for use in regulatory oversight. The main elements of these strategies are targeted quantitative hazard- and risk-based controls along the poultry chain, monitoring performance in meeting targets, safe food handling, and implementing these controls with commitment from all sectors involved. Success has been achieved more quickly in NZ that has the advantage of use of chemical decontamination during processing and was able to engage their industry made up of a few major companies. NZ invested in preliminary risk management activities to guide their strategy such as risk assessments, attribution studies of food source, reservoirs and amplifying hosts, combined with molecular typing to clarify transmission pathways, and combined this with risk assessments and cost-benefit analyses of interventions. Risk studies have been carried out in the EU and in addition the countries drew on the work and tools available from Codex/FAO/WHO.

All countries recommend voluntary measures on farm including on farm biosecurity, hygienic harvest (catching and depopulation) and transport, and controlled processing. Attention is paid to packaging of raw chicken, leak proof packaging in NZ and in the UK some retailers have taken up double bagging. Non-chemical treatments were investigated in the UK such as steam and ultrasound and blast freezing. In their strategies a processor can decide on control options appropriate for their establishment as long as they meet the *Campylobacter* performance target expressed as a quantitative food safety criterion for carcasses at the end of processing. In the UK, the initial target was to lower the prevalence of *Campylobacter* in chicken and had little success. This has been refined to a more risk based approach of lowering the prevalence of birds with the highest counts that are estimated to present the greatest risk. Again progress has been slow and greater commitment has been sought from all those involved in the food chain. In the USA, performance standards for *Campylobacter* and NTS were changed to include fabricated and comminuted products found to most accurately represent consumer exposure and the performance levels and sampling plans made more stringent to achieve levels assessed to result in acceptable levels of attributable illnesses following consumption of the products. The changes in the USA have been too recent to measure success.

Iceland has had notable success with its reduction strategy for campylobacteriosis in chicken that essentially is based on market incentives for processors using performance targets. All carcasses from positive flocks or slaughter batches have to be frozen or heat treated decreasing market value. On farm interventions include biosecurity, preference for no thinning, and fly control. Farmers tend to send birds to slaughter younger when prevalence is lower.

Raw fluid milk and raw milk cheeses are attributed among common food vehicles for campylobacteriosis in the USA. Control is hampered by the legalisation of these foods in many states as well as the illegal production and sale or importation of these products, often as ethnic specialties, and the selectiveness of groups within the population exposed. The regulators are working with specialty cheese processor groups to improve implementation of hazard analysis and risk preventive measures.

All countries invest in extensive consumer information and education activities. Those with successful control programs still have residual levels of campylobacteriosis above their desired targets and further sources of transmission are being sought.

Listeriosis

In each country the pattern of listeriosis, at risk groups and the main foods attributed have changed over time. There are various possible explanations: successful targeted control programs, changing demographic and socio-economic factors and food supplies, the unpredictable opportunistic nature of the bacterium, and enhanced epidemiological investigation with molecular typing of isolates. The basic preventive controls are common with RTE food manufacturers required to have HACCP based food safety programs essentially including product formulation, processing and ingredient control, worker training, building design, sanitation, and monitoring and record keeping, as well as mandated safety related date labelling. Large manufacturers and high end retailers have been successful in producing food with very low prevalence at the point of manufacture and sale, and a common focus is now on post-manufacturing risk management. Countries are cautious in setting health targets realising the pressures of at risk groups increasing, and the availability of chilled RTE food that will support growth expanding.

There are food safety microbiological criteria for *L. monocytogenes* in RTE foods in all countries. The USA has a zero tolerance for *L. monocytogenes* in post-lethality treated RTE foods. While this may be criticised theoretically, a performance target for industry has been a driver to improve practices. The UK and NZ have adopted a risk-based approach with criteria based on the ability of a RTE food to support *Listeria* growth during its shelf life, and the UK has more stringent sampling plans for *L. monocytogenes* in food for infants and in foods for special medical needs. All countries require environmental testing in processing areas.

In the UK, older adults and immune-compromised persons both in the community and in care, pregnant women from ethnic groups, and poorer communities often obtaining food from small to medium enterprises manufacturing and retailing riskier foods, have been identified at most risk. The UK strategy is to improve the compliance among those providing risky food for these groups and education and information materials for the groups themselves. Guidelines for those preparing and serving food to institutionalised persons have recently been prepared and the means to reach those at greater risk living out of care is being sought. Further, it has been observed that small and medium sized enterprises and enforcement officers have poor understanding of the newer standards for *L. monocytogenes* based on potential for growth. This has been identified as a need in training programs. In the USA, the Food Code has been amended to provide additional requirements in food service such as prevention of *Listeria* biofilms in the food service environment, the need to disassemble and scrub equipment regularly (4hr.) and to rotate sanitisers to avoid bacterial resistance. The FSIS is exploring further measures that can be taken at retail.

In the USA, fruits have emerged and dairy foods remain as the most important foods in food attributions studies and outbreaks have increased in size and distribution with changing food supply chains. Dairy products remain problematic due to the consumption of raw milk products and non-regulated processing in illegal networks. In addition, the potential for survival of *L. monocytogenes* in cheese under the 60 dy. aging rule has been challenged and regulators and industry are working to resolve the issue. The Produce Safety Rule recently introduced will include control measures for *Listeria* and further risk assessments are in progress e.g. use of manures as soil amendments. The USA has experienced listeriosis outbreaks caused by “novel” foods e.g. caramel toffee apples and stone fruit, which emphasises the potential for this ubiquitous environmental bacterium to find a niche in foods provided the conditions are favourable for survival and/or growth.

The NSW situation

Approach to pathogen reduction

The most striking difference in risk reduction approaches successfully implemented in the USA, UK and NZ is the overall risk management approach using health goals and making use of food safety metrics to set performance targets. This is particularly apparent for the zoonotic pathogens.

The pathogen reduction approaches in the USA, UK and NZ are designed to meet overarching health goals for their countries. No equivalents were identified for Australia. The NSW Government has taken a significant step in setting its own health goal of reducing foodborne illness by 30%. For the NSW FA risk managers to implement targeted risk reduction strategies to meet this higher level goal, similar to the approach in the reviewed countries, it would be necessary to further define a realistic health target for each of its priority foodborne illnesses and their contribution to the overall 30% target. The relevant agencies in the countries reviewed have developed targeted strategies to meet their goals and to measure progress against respective baseline foodborne illness rates at their commencement or later. Currently this is not possible in NSW as there is no surveillance of campylobacteriosis and there is limited current food and reservoir attribution data other than from outbreak investigations. These cases represent a small proportion of the total foodborne salmonellosis and campylobacteriosis cases reported and the latter is not often associated with outbreaks.

The agencies' strategies are based on risk, evidence and science and are implemented using a systematic risk management framework. They rely heavily on data on foodborne illness and food attribution, understanding the food-pathogen pathways, and quantification of the contribution of activities through chain to the final level of health risk using risk assessments. In this way they are able to estimate the potential reduction in human illness associated with specific foods and specific interventions and to prioritise activity to maximise the overall contribution to meeting health goals. To follow their example, the NSW FA would require significantly more information than that identified in this review and need to apply it in a more systematic framework with a focus on risk and quantifiable measures.

This report captured data in NSW from available reports; however, there are activities in progress in NSW and other jurisdictions and within industry that were not captured that could contribute to approaches similar to those taken by the reviewed agencies mentioned. Food attribution studies are underway in Australia and may require further support to produce timely results. There is an option to translate data from national databases or from studies in other States and Territories although this would need to be a valid translation. The NSW FA has been very pro-active in conducting programs for verification testing, monitoring and surveillance of contamination of a variety of foods produced under the Regulation. The number of samples tested has been small for some food groups using this approach and may not be state-wide at the point of consumer exposure. Mandatory regular testing in the countries reviewed provides data on current food chain performance and contamination levels and characteristics. The Key Performance Indicator Program for chicken meat is an initiative identified that should generate important data for that food group provided all establishments participate. Development of national performance targets for *Campylobacter* in chicken at the end of processing is another initiative and could be most effective if they are risk based and appropriately defined.

Quantitative risk assessment outcomes are widely used internationally and the NSW FA has been proactive in underpinning their Food Safety Schemes with assessments of risk. Some Australian risk assessments identified did not cover the whole food chain, lacked data, or were hazard identification studies. Proposed NSW FA research with industry groups such as AECL should enhance the risk

assessment for eggs allowing a clearer picture of the role of on farm control measures. The countries reviewed are incorporating molecular characterisation of pathogens in their studies and a similar approach using tools being developed in the NSW Food Strategy would provide an opportunity to strengthen these assessments.

Notwithstanding the success of some targeted programs reviewed, they can make only a contribution to the impact on the rates of specific foodborne illnesses with multiple transmission pathways. Countries are seeking further measures than the targeted foods to achieve the health goals required. This applies to Australia where for example 77% campylobacteriosis were estimated to be foodborne and 30% of foodborne cases were estimated to be linked with consumption of chicken suggesting there many other infection routes requiring intervention.

Salmonellosis

There are many similarities as well as differences between the NSW FA Food Safety Schemes and approaches in the reviewed countries. The NSW FA NTS strategy includes control of NTS in shell eggs, microbiological monitoring, training of food retailers and improved genotyping which in the absence of detail indicates a focus on eggs.

It has been argued in Australia it is difficult to compare NTS control strategies in SE endemic areas due to the characteristics of SE not endemic in Australia. Eggs have been the primary SE focus; however, as SE has come under control in eggs other serotypes have proportionately increased and in the USA there has been a rebound where chicken meat has increased in importance in SE transmission. With time, the scenarios are becoming less different. The EU has moved to risk-based regulation for NTS targeting “regulated” serotypes to focus on those causing human illness rather than all NTS colonising reservoir hosts. The USA also takes this approach in assessing performance in meat processing. This risk-based approach to monitoring could be considered by the NSW FA e.g. some of the most commonly isolated NTS types in raw foods such as chicken meat are not common in human infections.

The UK and the USA control approaches for eggs were implemented considering SE and include control of transmission from breeding flocks, on farm and post-harvest controls, and they are exploring further on farm control measures for all NTS types. On farm controls are not given the same level of importance in Australia; however, proposed research in egg production should help provide better grounds for this. The main difference identified between strategies in the UK, the USA and the NSW situation is setting risk-based NTS performance targets and mandatory testing programs for flocks and eggs, and flow on corrective actions to prevent contaminated food entering the marketplace.

The UK/EU focus is on farm with breeder and layer flock prevalence limits and testing programs. The USA expectation is controls should be equivalent to NTS reduction achieved by egg pasteurisation either through on farm measures and flock and egg testing programs or a pasteurisation treatment. These performance limits guide industry risk managers, provide incentives, and support regulatory oversight. Multiple interventions through chain provide the best overall outcome in achieving the health goals. Some interventions were singled out as having significant impact in helping to achieve targets. In the UK/EU and the USA uptake of vaccination of poultry results in reduction of flock prevalence for NTS or a serotype, refrigeration prevents NTS growth particularly when internalised in eggs, and use of pasteurised egg products in food service lowers attribution of certain raw egg-based dishes. UK farmer and industry quality assurance programs that have more stringent standards have been an important element in the success of their control strategies.

The approaches to control of NTS chicken meat in the UK and USA are similar to that for eggs where the main difference from NSW is again the use of performance targets. The UK has broiler flock prevalence targets and both countries have processing targets determined to reduce prevalence and contribute to lowering illness from consumption of these products. The USA has reviewed which meat and poultry products are associated with health risk and have adapted process verification programs accordingly and considered the need for labelling with safe handling and cooking instructions e.g. minced beef, chicken, not-ready-to-eat-products. The USA has the benefit, unlike the UK, of being able to use chemical decontamination to reduce NTS levels.

In the USA, fresh produce (seeded vegetables) has become the most frequently attributed food in salmonellosis cases. These have included both local and imported product where large production volumes were widely distributed. Australia has now experienced similar outbreaks. The USA has introduced a new Produce Safety Rule that is still a work-in-progress where the whole food chain will be required to implement hazard-based and risk prevention programs. The NSW FA is also collaborating externally on food safety and plant products and would be advised to be aware of developments in other countries.

Campylobacteriosis

The risk reduction approaches for campylobacteriosis in the UK, NZ and USA have primarily focused on chicken meat and NZ, that has been the most successful, is now investigating additional transmission routes to further reduce the incidence. Recommended approaches to control are not dissimilar to NSW including on farm biosecurity, hygienic harvest and transport, controlled processing (UK was not able to use chemical decontamination), and safe food handling.

Similar to salmonellosis strategies the main difference with the NSW approach is to set mandatory performance targets for raw chicken at the end of processing to drive change that would reduce the rate of illness following consumption of chicken meat to an acceptable level. The targets include sampling plans and acceptable levels of *Campylobacter* prevalence and/or the prevalence of product with high counts and have been applied to carcasses, portions and comminuted products. The targets provide a guide and incentive for industry who are able to choose their risk management options on farm, during transport and during processing with supporting regulatory guidelines. In NZ repeated performance failures could result in plant closure. Commitment of all those involved in the chicken meat chain and a culture of food safety is identified as an essential element for success in the UK and NZ. Iceland implemented a successful strategy that is also based on use of performance targets and market incentives for processors as all carcasses from positive flocks or slaughter batches have to be frozen or heat treated decreasing market value.

Listeriosis

There is a common trend in the USA, UK and NZ as in Australia where large manufacturers and retailers have generally complied with regulations and produce food with very low contamination rates with *L. monocytogenes*. The focus in the overseas countries has shifted to helping improve compliance among other small and medium size manufacturers and retailers producing these foods and to identify and provide education and information for at risk consumer groups who, in the UK at least, may also purchase food from these sources. The UK invests in social and behavioral studies to identify at risk consumers, their behaviours and practices, and risk factors, to give focus to their control approaches. Understanding of date labelling and food handling practice among older adults and understanding of more recent food standards based on growth of *L. monocytogenes* among retailers and enforcement officers are regulatory measures poorly understood and should be noted. The USA is continuing to investigate with industry improved measures for control of *L. monocytogenes* at retail/food service

and the validity of requirements in cheese manufacture. They have added requirements in the Food Code e.g. specific cleaning and sanitising schedules for equipment, as would be expected of manufacturers that could be considered in NSW. In the USA, fresh produce has emerged as an important food group in transmission of listeriosis and unexpected food scenarios have been linked with outbreaks. New initiatives in the control of pathogens in produce in the USA and in NSW are planned as discussed. In surveys in NSW, hygiene indicators were the common cause of compliance failures indicating need for ongoing improvement in basic hazard/hygiene regulations.

Technologies and other decontamination measures

The interest and acceptance of technologies and decontamination measures varied with country regulations. There are many studies of chemical decontamination agents although most result in about 1-2 log₁₀ reduction of pathogens. Bacteriophages have attracted renewed interest for use in production animals and birds (zoonotic pathogens), during processing, in products, and for environmental control and some have gained regulatory approval.

Non-thermal processing technologies have been available for some time, they result in equivalent pathogen reduction levels as thermal processing, and result in a better quality product although industry uptake has been slow. The EU has been investing in promotion of these technologies as an alternative to chemical treatments. In the UK, a commercial process using steam and ultrasound has been taken up by a poultry processor and reported to reduce *Campylobacter* on neck and breast skin by 80%.

Shell egg decontamination treatments have been investigated although not all result in a NTS reduction equivalent to a pasteurisation process criterion of a 5 log₁₀ reduction as required in the USA where they have to be combined with other interventions and refrigeration. There are patented thermal pasteurisation processes using water baths, pulsed light, ultra sound/thermal and radio frequency treatments. Lower reductions of about 2 or 3 log₁₀ reduction have been achieved using ionizing radiation, atmospheric cold plasma or microwave technology. The effects on egg functionality can be a limitation.

Conclusions

The approach to reduction of the risk of NTS, *Campylobacter*, *L. monocytogenes* in food in the USA, UK and NZ, and NSW and the approach of Codex have been extensively reviewed. There are similarities in the pathogen/food issues. There are 3 general scenarios observed. The zoonotic foodborne pathogen (NTS and *Campylobacter*)/pathways fell into 2 of these: primary products that have had mandated performance limits for a long time, and now of lesser importance in illness transmission, and, those with no equivalent performance limits historically, frequently attributed to illness now, and being addressed by implementation of mandatory performance limits. The third scenario includes *L. monocytogenes* for which performance limits were established and it has come under control in the pathways initially identified and by large manufacturers, and control approaches are being re-focused on post-manufacture handling, changing at risk groups and other foods. While the programs in these countries have generally shown evidence of success the level of success and the speed in achieving it differed.

The most outstanding difference between the current NSW situation and the reviewed countries is the overall regulatory approach. The overseas countries have established national health goals for specific foodborne illnesses and their agencies have designed targeted risk- and evidence-based pathogen reduction strategies to be implemented in a systematic management framework. This is closely aligned with the more recent works of Codex. Maintenance of basic hazard and hygiene

controls is mandatory and mostly, participants in the food chain choose their control measures with regulatory guidance as in NSW. The difference is the control measures have to result in a performance level that would meet mandatory quantitative targets set at effective risk reduction points in the food chain. The performance targets serve several purposes, to guide and incentivize industry risk managers, for regulatory process verification and monitoring, to measure progress and inform review and need for modification. In the event of failures corrective actions are enacted to protect the food supply.

While there are testing programs and limits in the NSW FA Food Safety Schemes Manual, many are for processed/manufactured foods, hygiene criteria or often food safety criteria for *L. monocytogenes*. There are recent initiatives for process verification testing for chicken meat where results are compared with 2006-2008 surveys to rate performance. There is an opportunity to establish risk-based food safety performance targets to guide pathogen reduction strategies.

The NSW Government has been forward thinking in setting a health goal for foodborne illness; however, for the NSW FA to operationalise this and measure progress, further breakdown to specific foodborne illnesses will be required. The NSW FA has been pro-active in basing its Food Safety Schemes on risk assessments. To take a similar approach to the countries reviewed a more advanced risk based and quantifiable approach would be required. The evidence base for this could draw on outputs of existing and planned programs and research, and additional knowledge gaps may need to be filled especially in the areas of disease surveillance, food and pathogen reservoir attribution, understanding transmission pathways from farm to plate, and risk factors.

There are few specific intervention measures that differed from NSW food chain practices. Widespread uptake of vaccination of poultry to control NTS is one and this is to be investigated by the FA together with the egg industry in the Food Strategy. Thermal and non-thermal technologies are effective although uptake varies considerably. These technologies are an attractive option for shell eggs although not all are equivalent to a pasteurisation process criterion as in the USA and the impact on egg functionality is variable. Bacteriophage is attracting increased interest through chain and decontamination using chemical rinses during processing is popular in the USA although restricted in the UK/EU.

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List of abbreviations

AECL	Australian Egg Corporation Ltd
AMR	Antimicrobial resistant
APC	Aerobic plate count
CAC	Codex Alimentarius Commission
CCFH	Codex Committee on Food hygiene
CDC	Centers for Disease Control and Prevention
CFR	Code of Federal regulations
CFSAN	Center for Food Safety and Applied Nutrition
cfu	Colony forming units
CI	Confidence Interval
CrI	Credible interval
DALY	Disability adjusted life years
DEFRA	Department for Environment Food & Rural Affairs
DHHS	Department of Health and Human Services
EFSA	European Food Safety Authority
EU	European Union
FAO	Food and Agriculture Organization
FCP	Food control programme
FDA	Food and Drug Administration of the USA
FD & C Act	Federal Food, Drug, and Cosmetic Act
FDOSS	Foodborne Disease Outbreak Surveillance System
FoodNet	Foodborne Disease Active Surveillance Network
FSA	Food Standards Agency
FSC	Food Standards Code, FSANZ
FSIS	Food Safety and Inspection Service
GBS	Guillain-Barré syndrome
GPH	Good Hygienic Practice
GMPs	Good Manufacturing Practices
GOPs	Good Operating Practices
GPRA	Government Performance and Results Act

HACCP	Hazard Analysis and Critical Control Point
HARPC	Hazard Analysis and Risk-Based Preventive Controls
IFSAC	Interagency Food Safety Analytics Collaboration
LEDS	Laboratory-based Enteric Disease Surveillance
MMWR	Morbidity and Mortality Weekly Report
NARMS	National Antimicrobial Resistance Monitoring System – enteric bacteria
NMD	National Microbiological Database
NNDSS	National Notifiable Diseases Surveillance System
NRTE	Not-ready-to-eat
MLST	Multilocus sequence typing
MVLST	multi-virulence-locus sequence typing
NTS	Non-typhoidal <i>Salmonella</i> , excludes <i>S. Paratyphi</i> also.
NZ	New Zealand
NZ MPI	New Zealand Ministry for Primary Industries
OIE	World Organisation for Animal Health
PFGE	Pulsed Field Gel Electrophoresis
PMO	Grade “A” Pasteurised Milk Ordinance
PPPS	Primary Production and Processing Standards
PR:HACCP Rule	Pathogen reduction: Hazard Analysis and Critical Control Point Rule
PS	Performance standards
PSR	Prevention status reports
PT	Phage type
PulseNet	National Molecular Subtyping Network for Foodborne Disease Surveillance
Quads	Quadrilateral Group (Codex)
RMF	Risk management framework
RMP	Risk management programme
RTE	Ready-to-eat
SD	Standard deviation
SE	<i>Salmonella</i> Enteritidis
SSOPs	Sanitation standard operating procedures
STEC or VTEC	Shiga toxin-producing <i>Escherichia coli</i> also referred to as VTEC, Vero toxin-producing

UK	United Kingdom
USA	United States of America
USDA	United States Department of Agriculture
WHO	World Health Organization
WGS	whole genome sequencing

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Introduction

The New South Wales Government has developed a visionary plan for the food industry, *NSW Food Safety Strategy 2015 – 2021*. Achievement of the strategy's goal includes reducing the number of foodborne illnesses in NSW by 30% and delivering safe superior-quality food to local and international consumers. A project was developed by the NSW Food Authority (NSW FA), in relation to this Strategy, *Food Safety Strategy: Reduction of foodborne illnesses*. In this project the NSW FA seeks to better understand foodborne illnesses and reduction strategies developed and adopted by different countries and to identify any gaps between international strategies and current strategies applied in NSW. The focus is on 3 target microorganisms, *Salmonella*, *Listeria monocytogenes*, and *Campylobacter*, and food allergen induced anaphylaxis, that are considered to be the most important causes of foodborne illnesses in NSW.

This project was undertaken to investigate these needs for the 3 microorganisms of interest and is the subject of this report. The project outcomes defined by the NSW FA included:

1. Generating a better understanding of the foodborne illnesses and reduction strategies developed and adopted by different countries, and,
2. Identification of the gaps between international strategies applied and current strategies in NSW.

The project outcomes would be achieved through the following project objectives to be conducted by the Contractor:

1. Summarise key aspects of risk reduction strategies for each of the pathogens non-typhoid *Salmonella* (NTS), *L. monocytogenes*, and *C. jejuni* (referred to as *Campylobacter* unless specified) when transmitted by food and spanning the farm to plate continuum in the United States of America (USA), New Zealand (NZ) and the United Kingdom (UK). These countries were agreed to by the NSW FA at the beginning of the project. Other European Union (EU) country activity will be referred to where relevant and in association with the UK as it is an EU member state.
2. Summarise the approach of the Codex Alimentarius Commission (CAC) Food Hygiene Committee (CCFH) to food safety risk management relevant to these pathogens as this is the reference for international trade and underpins the approach in these countries and Australia as member countries.
3. Identify new technologies and tools that could be used by risk managers in industry and government to strengthen risk reduction strategies for the specified 3 pathogens.
4. Assess the success of the respective country risk reduction strategies summarised where such information is available.
5. Conduct an assessment of the current approaches in NSW that may impact on the level of foodborne risk from the 3 identified pathogens and identify significant gaps between NSW and international approaches where they exist.

Project approach and limitations

Project approach

From hereafter *Salmonella* is used to refer to non-typhoidal serotypes of *Salmonella enterica* only and is abbreviated as NTS; however, other countries can differ from Australia in inclusion of serotype Paratyphi in this definition. *C. jejuni* is the main *Campylobacter* species of importance in human illness

although for brevity *Campylobacter* is used in the report to include both this species and others of minor importance.

The project was undertaken as a desktop study drawing on the knowledge and experience of the Contractor, and information available via internet sources such as those of governments and international agencies, industry and related websites, internet news sites and the published scientific literature, and personal contacts.

1. An electronic web-based search was undertaken for country level risk reduction strategies for foodborne NTS, *L. monocytogenes*, and *Campylobacter* among developed countries with a comparable food production and social setting to that of NSW. It was agreed with the NSW FA at the beginning of the project, the countries would include the USA, the UK and NZ with reference to other EU countries if they had strategies that differ significantly or have notable success in some aspect for the pathogen or a specific pathogen-commodity pair.
2. The search included the selected government's web-based material, publications in peer-reviewed literature and other web-based industry, academic and government publications. Strategies that spanned the farm to fork continuum for a commodity were sought primarily and other programs recorded if of noted success in risk mitigation.
3. A summary was prepared of the strategies identified for each of the 3 specified microbial pathogens by country highlighting key aspects. Aspects may include risk management decision approaches, risk management options chosen, implementation, monitoring and assessment of progress.
4. A summary was prepared of the CCFH's approach to pathogen – specific control approaches relevant to the 3 specified pathogens.
5. An electronic web-based search was undertaken and a summary document prepared for technologies that could be used in food production and processing to add value in specific risk reduction strategies.
6. Evidence for success of the strategies identified was sought during the search described in 2 and summarised.
7. An assessment of the current approach to foodborne illness risk reduction in NSW specifically as it relates to the 3 specified pathogens was conducted. Significant gaps between NSW and international approaches were assessed and documented where they exist.

Project limitations

There are limitations to this study. Countries have been reviewed at the national level and food laws and regulations are administered and enforced at state, local government, council and lands of traditional peoples' levels. It was not possible to review the lower levels in the hierarchy that may be more comparable with NSW working as a state within Australia. The food and associated industries along the food chain have made very significant contributions to reducing the risk of foodborne pathogens, at times undertaking research and data collection, and implementing self-regulation and extension work, before governments have acted. It was not possible to capture all of this contribution although some instances have been acknowledged. The pathogens are addressed separately although it is recognized that for industry and in practice the approaches overlap. In most country sections, only the priority food groups linked with the pathogens and which are part of targeted strategies are reviewed in detail. Some other food groups may either be under control or not identified as of high priority and their omission does not indicate they are not important. This should be borne in mind and

caution taken when comparing NSW with other countries as NSW has its own specific background and priorities that can differ from those of the countries reviewed.

This has been a desktop and electronic review, therefore it is possible that information other than that available in this format and works in progress may have been missed. Countries and States vary in the level of information made available and the ease of public access. Every effort has been made to provide internet links to references for readers.

Results

The risk reduction strategies in the CAC and the 3 study countries were observed to be a moving target that continues to evolve along with the countries' evidence bases and the multitudes of influential external factors e.g. economic, social and environmental changes, and changes in the food chains and consumer food preferences. The economic and health burdens of these foodborne illnesses and the drivers (e.g. health and trade) for foodborne illness control vary between countries and therefore so do their priorities, levels of investment and commitments to control strategies. The risk reduction approaches for each of the countries and the CAC have evolved through basic hygiene and hazard controls, to commodity specific approaches and more recently to pathogen specific approaches that may target specific commodities or even population groups. It became apparent when reviewing the country strategies that span the food chain continuum, that control is applied at multiple points and also that making an assessment of the success of the strategies is not a matter of describing ad hoc intervention measures at any one point. In addition, the success of the strategies is influenced by the external factors, drivers and regulatory context in which risk reduction measures are implemented.

In meeting the objectives, the results have been presented in the following manner. A summary of the CAC approach to control of the 3 pathogens is provided as the reviewed countries are members of the CAC, have provided significant input into CCFH works on these pathogens, and have subsequently adopted the CCFH approach to pathogen control, risk management and the use of food safety metrics. This is followed by a review of risk reduction approaches for the 3 pathogens in each of the USA, NZ and the UK with some reference to the EU. For each country, an overview of the country situation is presented first followed by approaches to risk reduction for the 3 pathogens. The country overview and the pathogens are generally approached using headings related to the CCFH risk management framework literally followed by the UK and the EU, NZ, and less formally in the USA.

1. Preliminary risk management activities:

Headings: Evidence for health and economic burdens of disease, Food attribution including risk assessment and risk profiling outcomes as relevant;

2. Identification and selection of risk management options and implementation of control measures:

Headings: Federal agencies, Food law and regulation, Risk management and regulatory approach

3. Monitoring and review:

Headings: Evidence for success.

The current approach in NSW review is presented using a similar approach and significant gaps or differences between NSW and international approaches identified. Finally, new technologies and tools that could be used by risk managers in industry and government to strengthen risk reduction strategies for the specified 3 pathogens are reviewed.

Codex Alimentarius

Codex Alimentarius means “Food Code” and was established by the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) to develop harmonised international food standards which protect consumer health and promote fair practices in food trade. Codex international food standards, guidelines and codes of practice are established to contribute to Codex’s mission. Australia as well as the USA, UK and NZ are member countries of Codex and Australia, NZ, USA and Canada form one of the Codex Quadrilateral Groups or “Quads” where for matters of common interest they work together and support each other in Codex meetings.

These countries have significant input into the Codex Committee on Food Hygiene (CCFH) deliberations, and as such, adopt the principles and approaches contained in CCFH documents on food safety and this is evident in their approaches to pathogen reduction discussed in this report. Examples of those Codex documents that influence the approach to reduction of the 3 pathogens of concern for the NSW FA are briefly summarised. The CCFH documents are not individually referenced as they can be accessed via the Codex website at <http://www.fao.org/fao-who-codexalimentarius/standards/en/> (Cited 02/04/16).

The food hygiene basic texts provide understanding of how regulations on food hygiene are developed and applied and are recommended to governments, industry and consumers. The General Principles cover the food chain from the primary producer to the consumer and promote a farm to plate hazard- and risk- based approach. In addition to the Codes of Practice and General Principles of Food Hygiene, there are Principles and Guidelines for the Conduct of Microbiological Risk Management with an Annex on Risk Management Metrics, for Risk Assessment and for the Establishment and Application of Microbiological Criteria for foods. Each of the countries has made use of these basic principles and approaches to risk management in addressing control measures for the pathogens in this review. NZ literally translated the Codex risk management framework in their Risk Management Strategies.

Codes of Hygienic Practice are available for commodity groups e.g. fresh fruits and vegetables, low-moisture foods, refrigerated packaged foods with extended shelf-life, meat, eggs and egg products and milk and milk products. These have or periodically have added to them Annexes addressing specific matters/products prioritised as of concern e.g. the fresh fruits and vegetables Code has annexes for sprouts and leafy greens.

While these Codes address pathogens that may be hazards to be controlled in a product generally, more specific pathogen-product combinations are addressed in Guidelines e.g. the control of *Listeria monocytogenes* in ready-to-eat foods and the control of *Campylobacter* and *Salmonella* in chicken meat. A draft guideline is in preparation for the control of nontyphoidal *Salmonella* in beef and pork and preliminary risk management activity is underway on STEC/VTEC in foods.

The more recent Guidelines e. g. *Campylobacter* and *Salmonella* in poultry meat (CAC/GL 78-2011) and *Salmonella* in beef and pork (CX/FH 15/47/5) include a systematic approach along the entire supply chain and allow different combinations of control measures to be developed depending on the country or other setting to meet a final food safety objective. The Guidelines follow the process flow path indicating at each step any Good Hygienic Practice (GHP)- and/or hazard-based controls that may be applied, including the level of pathogen reduction that could be expected under specific processing criteria at that step. Systematic reviews of scientific literature and expert opinions were used to develop the Guidelines. A tool, *Risk Management Tool for the Control of Campylobacter and Salmonella in Chicken Meat*, was developed to assist in evaluating the overall effectiveness of the applied interventions in that system to assist in deciding on risk management options. The online model can be used to compute the residual risk between a baseline process flow and a process flow

applying selected interventions as outlined in the guidelines using local data inputs. The tool is available at <http://www.fstools.org/poultryRMTTool/>.

Hazard Analysis and Critical Control Point (HACCP) systems included in the Annex to General Principles of Food Hygiene (CAC/RCP 1-1969) are being reviewed by CCFH. Risk management food safety metrics have developed since the introduction of HACCP and there is discussion as to whether HACCP should become a more risk-based system linked with public health outcomes (Buchanan, 2011). Buchanan (2011) suggests HACCP could be greatly enhanced by incorporation of risk metric concepts and supportive computerised decision tools.

United States of America

Evidence of the health and economic burdens of foodborne illness

The Centers for Disease Control and Prevention (CDC) in 2011 estimated that each year roughly 1 in 6 Americans were ill from foodborne diseases (CDC, 2014). This equates to approximately 48 million illnesses, 128,000 hospitalisations and 3,000 deaths annually. Of 47.8 million (28.7-71.1 90% CrI) estimated to be transmitted by food, approximately 20% are estimated to be caused by 31 known foodborne pathogen (CDC, 2014).

Table 1 Estimated annual number of domestically acquired food illnesses, hospitalizations and deaths due to 31 known pathogens and unspecified agents transmitted through foods, USA (Table modified from CDC, 2014)

Foodborne agents	Estimated number per year (90% credible interval) and percentages					
	Illnesses		Hospitalisations		Deaths	
	No./yr. (90% CrI)	%	No./yr. (90% CrI)	%	No./yr. (90% CrI)	%
31 known pathogens	9.4 million (6.6–12.7 million)	20	55,961 (39,534–75,741)	44	1,351 (712–2,268)	44
Unspecified agents	38.4 million (19.8–61.2 million)	80	71,878 (9,924–157,340)	56	1,686 (369–3,338)	56
Total	47.8 million (28.7–71.1 million)	100	127,839 (62,529–215,562)	100	3,037 (1,492–4,983)	100

In the 2011 report estimates, among the top 5 pathogens known to cause domestic foodborne illness, NTS (11%) and *Campylobacter* spp. (9%) rank 2nd and 4th respectively with norovirus (58%) first. For hospitalisations, among the top 5 pathogens, NTS infections (35%) rank highest with *Campylobacter* (15%) ranking 3rd, and for deaths NTS (28%) is the first of the top 5 pathogens with *L. monocytogenes* (19%) and *Campylobacter* (6%) ranked 3rd and 5th respectively.

The economic burden of the 15 pathogens responsible for 95% of the 9.4 million episodes of foodborne illness for which a pathogen cause could be identified was estimated to be \$US 15.5 billion annually. NTS, *Toxoplasma gondii*, *L. monocytogenes*, norovirus, and *Campylobacter* accounting for 90% of this economic burden (Hoffman, 2015).

Healthy People Initiative 2020 food safety goals

In 2010, the USA Department of Health and Human Services (DHHS) launched the Healthy People 2020 Initiative that specifies health objectives to be met by the end of 2020. In the food safety area, health objectives were stated with reduction targets for foodborne illness rates from defined baselines, with measurable objectives, and ten year targets for illness rates of selected foodborne diseases (USDHHS, 2014). These targets shown in Table 2 play a major role in the development of pathogen reduction approaches of federal agencies as they are used to develop strategies, to drive implementation and to monitor progress.

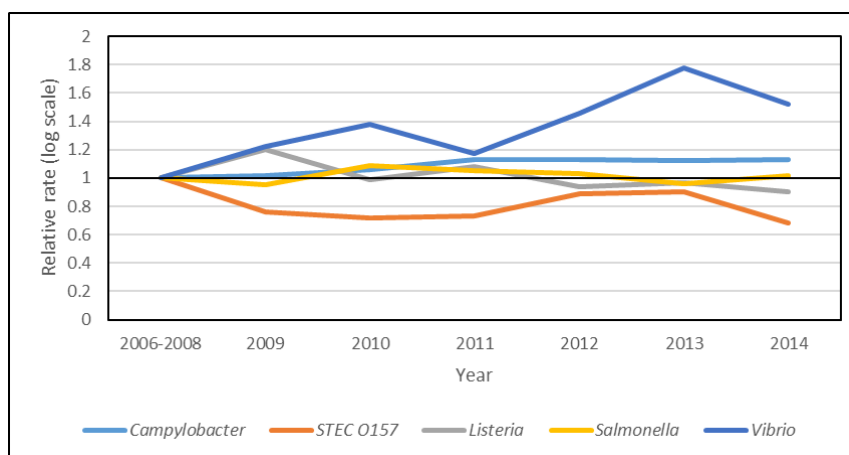
Table 2 USA Healthy People Objective 2020 for food safety and infections caused by *Salmonella*, *Campylobacter* and *Listeria monocytogenes* commonly transmitted through food. Data sourced from (USDHHS, 2014)

Health objective	Baseline 2006-2008	Objective target	Improvement level (%)
Reduce infections (cases/100,000 population) caused by pathogens commonly transmitted through food:			
<i>Salmonella</i>	15	11.4	24
<i>Campylobacter</i> spp.	12.7	8.5	33
<i>L. monocytogenes</i>	0.3	0.2	33
Reduce the number of outbreak-associated infections due to STEC* O157, or <i>Campylobacter</i> , <i>Listeria</i> , or <i>Salmonella</i> associated with:			
beef	200	180	10
dairy	786	707	10
fruits and nuts	311	280	10
leafy vegetables	205	185	10

*STEC = Shiga toxin-producing *Escherichia coli*

Trends on foodborne illness for 2014 were measured against previous years and the Healthy People 2020 targets based on data from FoodNet that monitors laboratory-confirmed cases from about 15% of the American population (MMWR, 2015a). Using this data set, the highest incidence (cases/100,000 population) among bacterial infections reported was for NTS (15.45) followed by *Campylobacter* (13.45) and the incidence of *L. monocytogenes* infections was 0.24. The relative rates for 2014 compared with the baseline from 2006-2008 are shown in Figure 1. *Campylobacter* was significantly higher with a 13% rise, NTS was not significantly different, *Listeria* was lower; however, they are all higher than the Healthy People 2020 target.

Figure 1 Relative rates of culture-confirmed infections of selected foodborne pathogens compared with 2006-2008 rates, Foodborne Diseases Active Surveillance Network, USA, 2006-2014 (Data from CDC at <http://www.cdc.gov/foodnet/trends/data-for-figures-2014.html#ui-id-5>)



* The position of each line indicates the relative change in the incidence of that pathogen compared with 2006–2008. The actual incidences of these infections cannot be determined from this graph. Data for 2014 are preliminary.

Food attribution

A novel method for estimation of foodborne illness source attribution for NTS, *Campylobacter* and *L. monocytogenes* with associated uncertainties was derived by the Interagency Food Safety Analytics Collaboration (IFSAC) to guide development of pathogen reduction strategies by the USA food regulatory agencies (IFSAC, 2015). Outbreak data from 1998 to 2012 was used; however, as 30% of salmonellosis outbreaks and 45% associated illnesses, 33% campylobacteriosis outbreaks and 17%

associated illnesses, and, 50% listeriosis outbreaks and 60% associated illnesses were found to have occurred between 2008 and 2012 these data were used as more current estimates. While IFSAC emphasised limitations in such studies they did conclude there were important pathogen-food links. The top source attribution estimates (90% CrI) for a pathogen and foods from the IFSAC model were as follows:

- Salmonellosis: 77% illnesses were attributed to seeded vegetables 18% (13-25), eggs 12% (9-17), fruits 12% (8-16), chicken 10% (7-13), sprouts 8% (5-12), beef 9% (6-13), and pork 8% (6-10),
- Campylobacteriosis: 74% illnesses were attributed to dairy 66% (57-74) and chicken 8% (5-12),
- Listeriosis: 81% illnesses were attributed to fruits 50% (5-77) and dairy 31% (12-64).

Federal agencies and food safety

The key Federal Agencies contributing to food safety and pathogen reduction for foodborne salmonellosis, campylobacteriosis and listeriosis, and others are the CDC, the Food and Drug Administration (FDA), and United States Department of Agriculture (USDA). However, there are some 14 collaborating federal agencies that have some responsibility for food as well as their state, local, tribal, and territorial counterparts and Alliances that have been established with research groups to address specific issues. Between the agencies, 3 elements in preventing foodborne illness are foodborne illness surveillance, protection of the food supply, and informed consumers.

The **CDC** provides the link between foodborne illness in people and the food risk management systems of the other agencies by providing epidemiological data/investigations, risk factors, illness alerts, and informing actions and policies among other activities (Cited 18/02/16 at CDC's Role in Food Safety at <http://www.cdc.gov/foodsafety/cdc-and-food-safety.html>). The role, of the CDC has become critical as control measures are to be evidence- and risk-based and measured against public health indicators.

CDC has multiple surveillance systems for microbial foodborne infections including:

- Laboratory-based Enteric Disease Surveillance (LEDS)
- National Notifiable Diseases Surveillance System (NNDSS)
- Foodborne Disease Active Surveillance Network (FoodNet)
- National Molecular Subtyping Network for Foodborne Disease Surveillance (PulseNet)
- National Antimicrobial Resistance Monitoring System – enteric bacteria (NARMS)
- Foodborne Disease Outbreak Surveillance System (FDOSS)
- Outbreak Response Team.

The **FDA** is an agency of the DHHS and has responsibility for protecting and promoting public health through the regulation and supervision of many areas, those with some relevance to foodborne pathogens including food safety, vaccines, animal food and feeds, and veterinary products. The FDA includes the Center for Food Safety and Applied Nutrition (CFSAN) as well as the Office of Foods and Veterinary Medicine and the Center for Veterinary Medicine (FDA, cited 17/02/16 at (<http://www.fda.gov/AboutFDA/Transparency/Basics/ucm192695.htm>)).

The **USDA** is responsible for USA government policy on farming, agriculture, and food among others and has programs to assist rural communities, promote agricultural trade and production, ensure food safety and food security, and to protect natural resources (USDA, Cited 17/02/16 at <http://www.usda.gov/wps/portal/usda/usdahome?navid=food-safety>). The Food Safety and Inspection Service (FSIS) is a USDA public health regulatory agency whose role is to ensure the USA's commercial supply of meat, poultry and processed eggs is wholesome, safe, and correctly labelled and packaged, through mandating the Poultry Products Inspection, Federal Meat Inspection and Egg Products Inspection Acts.

The specific foods covered by the FDA and USDA are not exclusive and some commodities are covered by both agencies at different stages in the supply chain so that a food facility can come under dual jurisdictional regulation for safe food production depending on the foods it handles. Broadly, FDA regulates foods including, dietary supplements, bottled water, food additives, infant formulas and other foods while the USDA plays a lead role in regulatory aspects of the commercial supply of meat, poultry and of egg products (not shell eggs that come under the FDA).

Executive agencies in the USA are required under the Government Performance and Results Act of 1993 (amended by the GPRA Modernization Act 2010) to develop strategic plans including annual performance management plans. The latter includes monitoring and measurement of achievement of performance goals which for agencies such as FSIS can include numerical targets for pathogen control in the foods under its jurisdiction. A key agency performance measure specific to the FSIS is the “All Illness Measure” (FSIS, 2015f). This metric provides an estimate of the total number of NTS, *E. coli* O157:H7 and *L. monocytogenes* foodborne illnesses associated with FSIS regulated products and is derived using a variety of data sources, including that from CDC and IFSAC.

Food law and regulation

A food is deemed to be adulterated under section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act (FD & C Act) (21 U.S.C. § 342(a)), if it bears or contains any poisonous or deleterious substance which may render it injurious to health and this is interpreted to include microbial pathogens. Consequences for violations of the FD & C Act may include seizure, injunction, and criminal prosecution. USA policy for food safety management has been progressively “modernising” since the 1980s towards a preventive approach with decision making based on science, evidence and public health risk, and covering the whole food chain continuum. This is aligned with the food safety guidance of the CAC for which the USA Government is a strong supporter and provides significant input.

The preventative approach has been progressively mandated by the dual agencies with risk management options having a common base of Hazard Analysis and Critical Control Point (HACCP), general regulations for Sanitation Standard Operating Procedures (SSOPs) and Good Manufacturing Practices (GMPs). FSIS established the final “Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems” (PR:HACCP Rule) in 1996 (FSIS, 1996). More specific directives have been added to these generic requirements and specific regulations established for specific pathogens or for pathogen/food pairs in response to evidence from public health surveillance or from food monitoring indicating the regulations were not achieving the level of health protection required. This has been the case with *L. monocytogenes*, NTS and *Campylobacter* in various high risk food groups e.g. meat and poultry, seafood, juice, eggs, ready-to-eat foods etc.

The most recent and considered the most far advanced Regulation is the Food Safety Modernization Act (FSMA) signed into law in 2011 and progressively being implemented by the FDA that has been given greater powers for its implementation (FDA, 2015h). The FSMA requires every registered food facility to implement HACCP-based food safety programs and further it requires identification and prevention of all reasonably foreseeable food safety hazards, not just those identified in a HACCP plan, whether naturally occurring or unintentionally introduced into the facility. Hazards can be biological, chemical, radiological or terrorist threats. A new term has been coined for this requirement called Hazard Analysis and Risk-Based Preventive Controls or HARPC. With HARPC, if there are unknown preventive controls for an identified hazard, research must be conducted regarding the preventive controls and their effectiveness validated at each food business for all their applicable products and processes. Any company or person not in compliance with HARPC can be criminally charged, have a public warning, or have suspension of registration, thereby preventing product from entering the USA market depending on the level of risk. Exemptions are the FDA regulated foods, those under the Produce Rule, seafood and juice HACCP Regulations previously established. Small and very small business are exempt which is a contentious point among food safety advocates.

USA regulatory approaches to pathogen reduction can include NTS, *Campylobacter* and *L. monocytogenes* if they are identified as hazards reasonably likely to occur in a food production/process and regulations can be pathogen and pathogen-food specific. Key regulations include:

- The FSIS PR:HACCP Rule for all meat and poultry processors fully implemented in 2000 (FSIS, 1996). It requires the implementation of HACCP and SSOPs in establishments and FSIS establishes metrics to be used in process control verification programs based on evidence of risk.
- The FDA FSMA requires the entire food industry under their control, including sectors from farm to table, and domestic and imported foods, to take the HARPC approach building on HACCP programs required previously for the meat and poultry, seafood and juice industries (FDA, 2015h). Performance Standards (PSs), inspection frequencies, testing, traceability and control of imports are expected to be based on levels of food safety risk.
- The FDA Food Code, last revised in 2013, is a model code that can implemented by food regulatory jurisdictions at all levels of government in a uniform manner and is a system of prevention and overlapping safeguards designed to minimize foodborne illness at the point where food is handed over to the consumer at retail and food service (USDHSS, 2013).
 - The Voluntary National Retail Food Regulatory Program Standards (Retail Program Standards) is intended to establish national uniformity through a set of recognized standards for retail regulatory programs that administer the Food Code (FDA, 2016c).
 - The Retail Food Safety Initiative Action Plan 2011, is a partnership between agencies, the retail food industry and state, local and tribal authorities with 4 functions: make certified food protection managers commonplace, strengthen managerial control and compliance, improve adoption of the Food Code, and enhance the regulatory environment for local food retailers (FDA, 2011b).
- FDA FSMA requires food safety programs to be written or overseen by trained persons who also must supervise the validation of preventive controls for identified hazards and maintain records (FDA, 2016b). The term “*preventive controls qualified individual*” refers to someone who has “*successfully completed certain training in the development and application of risk-based preventive controls or is otherwise qualified through job experience to develop and apply a food safety system*”. The approved curriculum for training is being develop and will likely vary with individual rules and be developed through various Alliances. The Produce Rule includes farmers as processors.

There are multiple other regulations and USA agencies providing compliance guidelines to support regulations, some of which target pathogens individually and in some cases pathogen-food pairs. The Guidelines often provide more information on the pathogen reduction approach and can be used by compliance investigators.

Compliance and enforcement

The FSIS and FDA conduct inspections, process verification testing, and microbiological surveillance programs to measure compliance. The FSMA includes new FDA risk-based inspection and compliance mandates (FDA, 2015g). All high-risk domestic facilities must be inspected within 5 yr. and no less than every 3 yr. thereafter. The FDA risk categorization process for facilities is data-driven and been presented in a decision tree format (FDA, 2015e). Within one year of enactment, the law directs FDA to inspect at least 600 foreign facilities and double those inspections every year for the next 5 yr. FDA will have access to records, including industry food safety plans and the records firms will be required to keep documenting implementation of their plans. The FSIS and FDA (FSMA) require certain food testing to be carried out by accredited laboratories and directs FDA to establish a program for laboratory accreditation to ensure that USA food testing laboratories meet high quality standards.

Under the FSMA, the FDA will conduct microbiological surveillance sampling that has been statistically designed for targeted high risk foods as USA consumers are likely to find them in the marketplace and over short time frames of 12-18 months (FDA, 2015i). The goals of the surveillance sampling are to prevent contaminated products from reaching consumers, to facilitate a greater understanding of hazards, and to generate data for short and long term decision making. The FDA will also conduct whole genome sequencing (WGS) on isolates. For example, in 2016 the FDA will sample and test 1,6000 samples of both cucumbers and hot peppers for NTS and STEC O157 as they have been the source of significant recent outbreaks.

The FSIS mandates the establishment of food safety PSs for pathogenic microorganisms on raw meat and poultry products through its PR:HACCP Rule. PSs articulate the health objectives into meaningful targets for industry and for their establishment process control verification programs. The approach is based on food safety metrics in line with the CCFH approach and are discussed in the specific pathogen sections that follow. At the agency level, whether the standards are met is used as a proxy measure of heightened or lowered exposure potential to the public.

The FSIS in 2013 launched their Public Health Information System, that is a web-based system used to integrate data and has 4 components: domestic inspection, import activities, export activities and predictive analytics. This is expected to allow them to be ahead of threats by allowing analysts to identify trends that will automatically adjust domestic and import inspections and sampling, e.g. the relationship between NTS test results and inspection findings, notifying field and headquarters' personnel about potential public health threats (Cited 10/03/16 at <http://www.fsis.usda.gov/wps/portal/fsis/topics/inspection/phis/phis>).

Importance of food safety risk in control measures

The modern direction unfolding for USA regulation, particularly with regards to pathogen control, is heavily reliant on estimating levels of food safety risk e.g. in categorising facilities, prioritizing foods, and measuring compliance. The FSMA requires the FDA to review epidemiological data every 2 yr. to ensure currency of the risk level categorization and identify any need for change (Smith Dewaal and Plunkett, 2013). Domestic facility risk categorizations are based on historical evidence of association with outbreaks, Class I recalls and compliance histories (FDA, 2012; FSIS, 1999) and the designation of high risk foods may be determined using a semi-quantitative risk ranking approach (FDA, 2014). There is significant reliance on a broad range of data that may vary in availability and quality. Public health surveillance data is key and the need for enhancement of the nation's current surveillance capacity coordinated by CDC and meaningful usage of this data by the FDA and USDA in their tripartite roles is recognized in the FSMA. Further, the ISAC was created in 2011 so agencies could share their goals to improve data and methods used to estimate foodborne illness source attribution, and to do this in a timelier manner for 4 key high priority foodborne pathogens, NTS, *Escherichia coli* O157, *L. monocytogenes* and *Campylobacter*.

Non-typhoidal *Salmonella*

Public health and economic burden in the USA

In 2011, in estimates of 31 major causes of bacterial infections commonly transmitted by food, NTS was ranked second (11%), after norovirus, causing 1,027,561 (644,786–1,679,667, 90% CrI) cases/yr., 19,336 (8,545–37,490, 90% CrI) hospitalisations/yr. and 378 (0–1,011, 90% CrI) deaths/yr. (Scallan et al., 2011). NTS infections ranked highest with toxoplasmosis in estimates of the economic burden of foodborne illnesses due to the number and severity of illnesses and cost \$US 3,666.6 million/yr. (Hoffman, 2015).

In 2014, FoodNet reported 7,452 culture-confirmed salmonellosis cases (15.45 cases/100,000 population) representing 38% of the total culture- and laboratory-confirmed bacterial and parasitic infections (MMWR, 2015b). There were 2,141 hospitalisations (29% total) and 30 deaths (0.2% total)

reported. The number of cases was not significantly changed compared with the Healthy People 2020 reference point in 2006-2008 (Figure 1). A particular concern was the contrast with STEC O157 that had decreased 32% as these pathogens can be transmitted by the same foods and can be subject to the same regulatory controls, indicating some different risk factors may be involved. In 2014, there were 193 culture-independent reports. In 2014 6% NTS infections were linked in outbreaks that were both small and local, and very large and multistate (MMWR, 2015b).

The emergence of antimicrobial resistant (AMR) NTS strains is an additional concern. In an assessment of AMR threats in the USA by CDC and the FDA, NTS were rated as a “serious” threat (USDA/CDC, 2013). While NTS were not considered an urgent threat, it was considered these threats could worsen and may become urgent without ongoing public health monitoring and prevention activities.

Serotypes and genotypes

While the number of salmonellosis cases has not changed significantly since 2006-2008, the serotypes of isolates have (MMWR, 2015b). In 2014, of 6,565 (88%) serotyped NTS, the number (incidence per 100,000 population) of the top 6 serotypes were as follows: Enteritidis 1,401 (2.90), Typhimurium 806 (1.67), Newport 724 (1.50), Javiana 639 (1.32), I 4, [5],12:i:- 381 (0.79), and Infantis 235 (0.49). Compared with 2006–2008 cases there were significant changes: Typhimurium decreased 27% (Confidence Interval (CI) 18%–35%), Infantis increased 162% (CI 100%–244%) and Javiana increased 131% (CI 83%–191%).

Typhimurium was the most common serotype reported to FoodNet until 2009 and has been declining since the mid-1980s. *S. Enteritidis* (SE) cases and outbreaks increased in the 1970s and 1980s to become the most common NTS infections in the early 1990s resulting in regulatory actions. SE infections declined in early 1990 only to rebound to higher levels in the 2000’s and to be responsible for several high profile outbreaks, particularly among the young and elderly (Chai et al., 2012).

Molecular methods are used to type NTS isolates and Pulsed Field Gel Electrophoresis (PFGE) results are included in the PulseNet database. WGS is a valuable additional tool in understanding NTS epidemiology and a need for increased completeness of typing of case isolates for the CDC’s PulseNet and NDDSS was highlighted in the 2015 Prevention Status Reports (CDC, 2016d) and in other agency strategic plans.

Food Attribution

IFSAC estimated foodborne illness source attribution for NTS, derived from outbreak data from 1998 to 2012, for food regulatory agencies (IFSAC, 2015). The source attribution estimates (90% CrI) for 77% salmonellosis foodborne outbreaks included seeded vegetables 18% (13-25), eggs 12% (9-17), fruits 12% (8-16), chicken 10% (7-13), sprouts 8% (5-12), beef 9% (6-13), and pork 8% (6-10). IFSAC noted there was greater confidence in the attribution estimates for NTS with narrower CrIs than other pathogens and flagged the particular complexity of NTS control as multiple foods and systems need to be addressed. Outbreaks associated with raw, not-ready-to-eat (NRTE) stuffed chicken products (e.g. chicken Kiev and stuffed chicken products) occurred from 2013 through 2015 presenting a specific category of poultry to be addressed (FDA, 2015c).

Multi-state outbreaks are not uncommon and foods linked with more recent such outbreaks, 2010-February 2016, are shown in Table 5. Foods/ingredients in these outbreaks were not dissimilar to many others between 1998-2012 although imported foods have become an issue. Notable among recent multi-state outbreaks are the produce, low moisture nut/seed/spice products, diet supplements and raw fish used in dishes such as sushi, that may not receive a heat lethality treatment before consumption. These may reflect on, among other factors, changing food preferences and food chains.

Risk management and regulatory approach

The USA Healthy People 2020 target for reduction of human salmonellosis is about 25% (USDHHS, 2014). Risk reduction strategies for the priority risk foods for NTS come under both FDA and USDA jurisdictions. Rationale and approaches to NTS control is described with special attention to the high priority foods only.

FSIS regulated foods

Progress in reduction of salmonellosis linked with FSIS regulated foods was slow so the FSIS developed a *Salmonella* Action Plan in 2013. The “FSIS attributable” salmonellosis cases were determined to inform the plan (FSIS, 2016d). FSIS estimated about 33% all salmonellosis cases were associated with FSIS-regulated products; poultry represented about 58% of these cases of which 85% were associated with chicken and 15% associated with turkey (FSIS, 2015b). NTS comprised ~95% of all estimated illnesses in their All-Illness Measure (FSIS, 2016d). The priority list of actions and expected outcomes are presented in Annex 1. They include modernising inspection and enforcement to be risk and evidence based and supportive of establishment improvement, more targeted sampling, further investigation of transmission pathways, and improved education for the public. Background to the actions is reviewed for the specific foods.

Meat and poultry

Beef

USDA federally inspected meat and poultry plants are required to comply with the FSIS PR:HACCP Rule (FSIS, 1996) which specifies implementation of HACCP plans, SSOPs and PSs. The Rule was in part initially driven by STEC O157 concerns in beef that resulted in inclusion of these specified intervention requirements:

- all slaughter establishments use at least one effective antimicrobial treatment to reduce harmful bacteria, and,
- standards for cooling red meat carcasses to prevent the growth of harmful bacteria.

Ground beef

Over the last 38 years salmonellosis outbreaks linked to beef occurred at about 2/yr. and in the 1970-80s roast beef was predominantly implicated (Laufer et al., 2015). The FSIS investigations of commercial pre-cooked roast beef outbreaks revealed cooking practices provided inadequate lethality treatments and a series of regulations were developed defining cooking parameters for temperatures and times, and humidity (FSIS, 1999).

A change in food attribution to ground beef related outbreaks from 2002-2011 and the emergence of AMR strains, e.g. *S. Newport* and *S. Typhimurium* DT 104, have re-focused attention to NTS in ground beef, Annex 1, Action 8 (Laufer et al., 2015). STEC O157 illnesses linked to undercooked ground meat products were a key driver for FSIS PR:HACCP regulations and specified STEC serotypes have been declared adulterants in ground beef, although not NTS. Regulatory control has been progressively tightened with requirements of more stringent sampling plans and more sensitive test methodologies and the use of multiple pathogen reduction methods during slaughter are now common e.g. carcass decontamination, steam vacuuming and pasteurisation (Laufer et al., 2015). This has been successful for STEC illnesses linked to ground beef as they have decreased in contrast to NTS illnesses where rates were not significantly different. Although ground beef products were NRTE products and NTS was not an adulterant in beef, the FSIS stated it would consider products linked with outbreaks to be adulterated and some large recalls e.g. 450,000 pounds (204,117 Kg) have occurred.

Various factors have been hypothesised to contribute to increased links of NTS with ground beef: national consumption of ground beef has decreased although consuming undercooked burgers has

increased, increased consolidation and complexity in the industry, co-mingling of sourced carcasses into larger product lots and larger product distribution networks, increased use of PulseNet to link human cases (Laufer et al., 2015). An anomalous finding was a higher level of NTS in ground beef than on the carcasses from which it was derived. Salmonellae can localise in the peripheral lymph nodes of cattle where they are protected from carcass decontamination processes and these lymph nodes are not all removed during routine carcass dressing. Investigations are ongoing on the significance of lymph nodes in ground beef contamination, risk factors for infection, and new approaches for control.

Mechanically tenderised beef

STEC O157 illnesses have been linked with consumption of mechanically tenderised beef in the USA and Canada (FSIS, 2015c). As a result, in 2014, Health Canada published an amendment to the Canadian Food and Drug Regulations Gazette Part II that requires any mechanically tenderized beef sold in Canada to be labelled as such and the inclusion of safe cooking instructions (Canada, 2014). The FSIS announced in 2015 an amendment to the Federal meat inspection regulations requiring labelling similar to Canada. Requirements are *“the use of the descriptive designation “mechanically tenderized,” “blade tenderized,” or “needle tenderized” on the labels of raw or partially cooked needle- or blade tenderized beef products, including beef products injected with a marinade or solution, unless the products are to be fully cooked or to receive another full lethality treatment at an official establishment* (FSIS, 2015c). Labels on raw products destined for food service or home cooking will have to include validated cooking instructions e.g. mechanically tenderized beef be cooked to a minimum internal temperature of 145°F (63°C) followed by a 3 min. rest time and products have to be turned at least once during cooking. NTS have not been linked with these outbreaks and there are differences with STEC O157 such as the few cells that often result in illness compared with NTS. The FSIS in its guidelines for cooking of this product type uses a process criterion of 5 log₁₀cfu/g reduction for NTS as NTS are considered an indicator for pathogen lethality in cooking.

Poultry

NTS and *Campylobacter* are considered together in FSIS food safety measures for raw poultry as they are the most frequent microbial hazards “reasonably likely to occur or emerging in their process” and therefore have to be included by industry in their HACCP plans. FSIS introduced PSs for whole chicken in 1996 with the PR:HACCP Rule. Driven by the Healthy People 2020 goal and with several outbreaks from 2010 linked to contaminated raw poultry products, the FSIS has investigated raw poultry contamination more broadly. In a retail poultry survey, 2012, 85% poultry available to consumers was chicken and 80% was in the form of chicken portions or parts (FSIS, 2015h).

The FSIS Compliance Guideline for control of NTS and *Campylobacter* in poultry outlines combined approaches for the pathogens as they would be considered in industry (FDA, 2015c). These are summarised in Annex 2 and cover, pre- and post-harvest and further processing sectors.

In their cost-benefit analysis of control options, FSIS considered possible changes that industry could make included:

- pre-harvest interventions, such as vaccination programs, well-timed feed withdrawal, clean and dry litter and transportation, and supplier contract guarantees of pathogen-free flocks.
- during processing, establishments could add additional cleaning procedures, apply chemical antimicrobials to fabricated portions and source materials used for comminuted poultry products, and provide additional sanitation training for employees.

RTE and NRTE meat and poultry products

NTS are considered adulterants in ready-to-eat (RTE) meat and poultry products. These products are divided into 5 categories, based on the type of processing: dried, salt-cured, fermented products, cooked or otherwise processed whole and comminuted products, and thermally-processed, and commercially sterile products, and are also regulated under 9 Code of Federal Regulations (CFR) and its various parts. Pathogen lethality PSs apply and compliance guidelines are provided (FSIS, 2012b). Except for thermally-processed, commercially-sterile products, the lethality PSs for all RTE products require a 6.5 log₁₀ reduction of NTS throughout finished meat products and a 7.0 log₁₀ reduction throughout finished products containing poultry, or a validated equivalent. Lower reductions e.g. 5 log₁₀ NTS in beef can be implemented where other more stringent controls or additional controls are verified and applied. FSIS conducts both random and risk-based testing programs at establishments based on 325g samples (FSIS, 2016b).

Partially cooked but NRTE food such as stuffed chicken entrees attributed in recent outbreaks do not receive this lethality treatment. The FSIS will address whether mandatory additions to labels of processed NRTE products that appear RTE are required e.g. "raw meat/poultry, for safety cook thoroughly" or an alternative, at an upcoming public meeting (Cited 20/03/16 in USDA notices at <http://www.fsis.usda.gov/wps/wcm/connect/c98df493-56ff-4052-b33f-1e680c703503/2016-0005.pdf?MOD=AJPERES>).

Consumer education

Federal agencies are proactive in providing information and education for consumers. They universally recommend the use of thermometers to measure the internal temperature of food during cooking and in refrigerators to ensure safe storage temperatures e.g. see <http://www.fda.gov/Food/ResourcesForYou/Consumers/ucm255180.htm>.

FSIS process control verification testing programs

Verification of sanitary slaughter and dressing depends on organoleptic inspection and FSIS inspectors apply a zero-tolerance PS for visible faeces and ingesta on dressed carcasses. Microbiological PSs and criteria for raw meat and poultry products are used as measures of process control and pathogen reduction performance in individual establishments and to allow establishments to calibrate their HACCP systems. Quantitative generic *E. coli* testing is used as an objective indicator of the adequacy of process control for faecal contamination. NTS is the target pathogen for pathogen reduction PSs based initially on national baseline prevalences determined (with the exception of young chicken and turkey carcass) prior to implementation of the regulation.

Raw products with established PSs or guidance have included carcasses of cows/bulls, steers/heifers, market hogs, young chickens and young turkeys and NRTE processed products included ground beef, ground chicken, and ground turkey. In 2011, FSIS discontinued NTS testing on market hogs, cows/bulls, and steers/heifers due to low levels detected and began testing ground chicken and turkey and will test chicken parts from hereon.

Beef. Since 2006, sample scheduling of beef processing establishments has been risk-based rather than random with focus on those establishments with the highest number of NTS positive samples and those with serotypes most frequently associated with human illness (FSIS, 2015g). Establishments are categorised 1-3 according to performance with category 3 the poorest. A "moving window" approach is now used (See Annex 1, Action 6) as the decision criterion, which consists of having fewer than a specified number of positive samples within a specified time frame (Buchanan and Schaffner, 2015). Buchanan and Schaffner (2015) point out the PSs used in the FSIS statistical process control approach are not actually a "pathogen removal" criterion as for an adulterant in a RTE food, rather it

is used as an indicator organism. They further comment the FSIS now largely ignores the industry *E. coli* data which they believe could be useful in assessing control programs, in demonstrating continuous improvement, and in identifying additional risk factors.

Pork. FSIS announced in 2014 plans to begin a Raw Pork Products Exploratory Sampling Program to be completed in 2015 to collect data on the presence of NTS, other pathogens, and indicator organisms in various pork products at retail and slaughter and processing establishments. A PS for pork may be forthcoming (Annex 1, Action 2).

Poultry. Previously the poultry PSs applied to carcasses only. However, the 2012 national baseline prevalence survey estimates of NTS and *Campylobacter* in raw NRTE poultry indicated the level of contamination increased post-fabrication and was highest in the most commonly consumed products, especially for NTS as shown in Figure 2 (FSIS, 2015h). The Figure includes annual prevalence rates from verification testing for 2012 to provide an idea of the annual carcass contamination rate; however, it was not part of the same survey (FSIS, 2015g).

Figure 2 Prevalence of *Salmonella* and *Campylobacter* detected in a national baseline survey of raw poultry by FSIS in 2012 (FSIS, 2015h) and annual prevalence for carcasses in 2012 from the Progress Report (FSIS, 2015g)

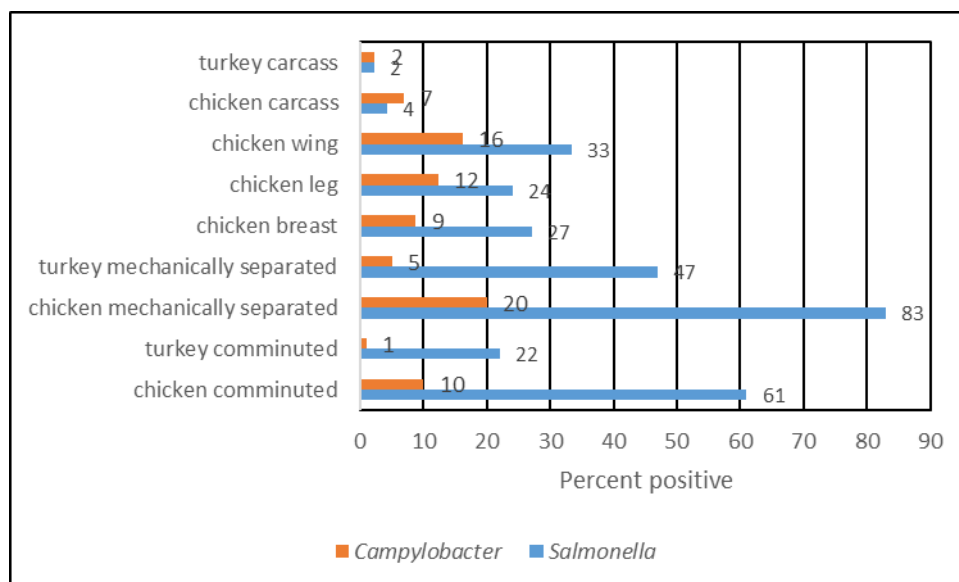


Table 3 Performance standards for raw poultry in the USA commencing May 2016. Data taken from FSIS Docket No. FSIS-2014-0023 (FSIS, 2016e)

Product (sample size)	Maximum acceptable percent positive samples		Performance standard*	
	<i>Salmonella</i>	<i>Campylobacter</i>	<i>Salmonella</i>	<i>Campylobacter</i>
Comminuted chicken (325g)	25.0	1.9	13 of 52	1 of 52
Comminuted turkey (325g)	13.5	1.9	7 of 52	1 of 52
Chicken parts (4lb or 1.8Kg)	15.4	7.7	8 of 52	4 of 52

*FSIS intends to interpret results within a moving window comprising fewer than 52 samples (n) by establishing a number of positive samples (s) such that $(s-1)/n < p \leq s/n$, where p is the maximum percent positive that would meet the performance standards.

FSIS estimated among salmonellosis cases caused by consuming chicken, 81% were associated with parts, 13% with whole carcasses, and 6% with comminuted product. Based on this accumulating evidence FSIS tightened the PSs using a risk assessment to relate PSs for chicken products with reduction of illness (FSIS, 2016e). As a result, the FSIS introduced a pathogen reduction PS for all

poultry products that should achieve at least a 30% reduction in NTS illnesses for chicken parts, comminuted chicken, and comminuted turkey as shown in Table 3 (FSIS, 2015b). Large establishments will be sampled weekly and smaller ones proportionately less often and performance history will be considered in risk level. Once a full set of testing under the new standards is completed, the FSIS will begin posting online which facilities pass, meet or fail the new standards in an effort to encourage improvement.

Eggs

Shell eggs

NTS risk management of shell eggs has been focused on SE since the emergence of SE as major cause of foodborne salmonellosis with shell eggs the primary source and it takes into account the ability of SE to be internalized in eggs (FDA, 2009). A farm to table risk assessment was conducted for SE in eggs and egg products by FSIS and FDA. The FDA Egg Safety Rule for shell eggs, finally codified at 21 CFR part 118, came into effect in 2010 and applies to shell egg producers with $\geq 3,000$ laying hens whose shell eggs are not processed with a treatment, e.g. pasteurization, to ensure their safety, and to those who transport or hold shell eggs for shell egg processing or egg products facilities where eggs come from farms with $\geq 3,000$ laying hens. Implementation of the Rule was expected to prevent approximately 79,000 cases of foodborne illness per year and 30 deaths caused by SE.

The Egg Safety Rule (FDA, 2009) requirements include the following (US FSA cited 17/05/16 at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm218461.htm>).

Egg producers whose eggs are not processed with a treatment, such as pasteurization (defined as a process that achieves at least a 5 \log_{10} reduction in NTS) must:

- purchase chicks and hens from suppliers with NTS control programs;
- prevent SE egg contamination during production on farm - establish pest and rodent control and biosecurity measures;
- conduct testing in the poultry house for SE. If the tests are positive, a representative sample of the eggs must be tested over an 8 wk. time period (4 tests at 2-week intervals); if any of the 4 egg tests are positive, the producer must further process the eggs to destroy the bacteria, or divert the eggs to a non-food use;
- clean and disinfect poultry houses that have tested positive for SE;
- prevent SE growth during storage and transportation - refrigerate eggs at 45°F (7.2°C) during storage and transportation no later than 36 hr. after the eggs are laid (this requirement also applies to egg producers whose eggs receive a treatment, such as pasteurization);
- maintain records including an SE prevention plan;
- register with the FDA;
- have a trained supervisor responsible for ensuring compliance with the SE prevention plan.

Further guidance is provided such as for egg production systems with layer hens having access to the outdoors. The FDA recommends additional controls such as vaccination and treatment of feed and water, although they are not in the Rule. The poultry industry and some states have been proactive in implementing control measures, including vaccinations for Typhimurium and SE prior to the Rule.

The FDA in partnership with the States uses a risk-based inspection strategy of egg farms using risk criteria including the number of laying hens, registration status, public health risk (whether or not the farm or company had been associated with previous recalls, outbreaks or consumer complaints), and other indicators that could impact how a farm implements food safety measures. There is a sampling strategy for SE that includes on farm environmental sampling when any group of hens is 40-45 dy. old and 4-5 wk. after the end of molt, and egg sampling of 1,000 intact eggs, representative of a day's production, conducted at 2-week intervals (See the Egg Rule at a Glance at

<http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM232271.pdf>). There is a systematic flow of testing where positive environmental samples require diversion of flocks or the egg testing, and if egg tests are positive this leads to diversion of eggs and further repeat testing until flock and egg tests are negative after which monthly egg tests are required.

According to the Food Code (FDA, 2013c) the following label is required on raw shell eggs in the marketplace. *'SAFE HANDLING INSTRUCTIONS: To prevent illness from bacteria; keep eggs refrigerated, cook eggs until yolks are firm, and cook foods containing eggs thoroughly.'* Further, in subparagraph (4) it states, *"Shell eggs that have been, before distribution to consumers, specifically processed to destroy all viable Salmonella shall be exempt from the requirements of paragraph (h) of this section."*

Egg products

The FSIS verifies shell eggs packed for the consumer are labeled "Keep Refrigerated" and stored and transported under refrigeration and ambient temperature of no greater than 45 °F (7°C) and FSIS provides consumer education on the safe handling of eggs.

The FSIS inspects all egg products, defined as eggs that are removed from their shells, at USDA inspected plants. This includes egg products, with and without added ingredients, with the exception of those products exempted under the Egg Products Inspection Act (EPIA) and officially inspected egg products bear the USDA inspection mark. The 1970 Egg Products Inspection Act (EPIA) requires that all egg products distributed for consumption be pasteurized and process criteria are regulated.

Egg products under the jurisdiction of USDA/FSIS have not been under HACCP regulations. Each month, FSIS inspectors collect one egg sample per process (7 categories of liquid and dried eggs) from each egg product processing plant and its Field Service Laboratories tests samples for the presence of NTS (FSIS, 2015e). This can result in inspectors sampling an egg product production plant as many as seven times per month depending on the number of plant production processes occurring during the month. From 2008-2014 there were 0.19% samples positive for NTS.

The Food Code 2009 Chapter 3 specifies that shell eggs, when prepared in food service, are to be cooked to specified temperatures for a specified time e.g. shell eggs broken and prepared cooked at 63°C (145°F) or above for 15 seconds (FDA, 2013c). If the egg is not served immediately, hot and cold hold temperatures are specified. The Food Code further specifies that pasteurized eggs be substituted in delicatessen and menu items that typically contain raw eggs unless the consumer is informed of the increased risk. Pasteurized egg substitution is specified for eggs that are for food service of vulnerable individuals.

Produce

The USA has experienced large salmonellosis outbreaks and recalls linked with a broad range of local and imported produce (Table 5). Previously, FDA's oversight of produce safety was mostly through voluntary guidance e.g. Good Agriculture Practices (GAPs), and other industry-driven initiatives e.g. third-party audits and GAPs certification, individual State initiatives and international schemes (Allan, 2013). Produce is now regulated under the new FDA FSMA Produce Safety Rule which for the first time provides science-based minimum standards for the safe growing, harvesting, packing, and holding of produce grown for human consumption on both domestic and foreign farms (FDA, 2015f). The definition of "farm" now includes growing, packing etc. and a category Secondary Activities Farm created. A "Qualitative risk assessment of risk to public health from on-farm contamination of produce" 2013 was used in development of the Rule. Implementation will be based on a risk prioritization of produce groups. FDA estimates that about 332,000 total illnesses per year are expected to be prevented by the provisions of this Rule.

Specific guidelines have been available for industry for the minimization of food safety hazards of produce groups linked with significant illness rates (e.g. leafy greens, melons, tomatoes) that cover both pre- and post-harvest sectors and these are available on the FDA website (cited 16/03/16) at <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/default.htm>. The Produce Safety Rule requires registered facilities producing produce, specifically fresh fruits and vegetables, mushrooms, sprouts, and peanuts and tree nuts, to comply with the general FSMA requirements for preventive food safety plans. Some new and specific requirements for produce are listed below and further details of these are provided in Annex 3.

Registered facilities will be subject to a risk-based inspection schedule with extra testing specified for some products. NTS lethality treatments are specified for various foods that are RTE and lethality performance criteria vary with the product e.g. nuts 4-5 log₁₀ reduction.

The first of FDA's targeted surveillance sampling program under the FSMA included mostly produce with 800 samples of each of sprouts and whole fresh avocados to be tested for NTS, *L. monocytogenes* and O157 STEC; in 2016, 1,600 samples of each of cucumbers and hot peppers will be tested for NTS and O157 STEC (FDA, 2015i). With safe practices, contamination of produce is difficult to detect and requires large sample sizes and time. For example, the USDA tested produce for NTS in their Microbiological Data Program that ran between 2001-2012 and found a prevalence rate of 0.34% for NTS in cilantro, known as coriander in Australia (Reddy et al., 2016). Some of the most common serotypes were common in human illnesses and produce and there was diversity and also similarity among the PFGE patterns of NTS produce and meat isolates.

Sprouts are given special attention due to the high attribution rate in outbreaks (IFSAC, 2015). FDA used a risk assessment to determine the impact of risk mitigation measures on risk reduction and to underpin the new requirements for sprouts in the Produce Safety Rule (Ding and Fu, 2016). The assessed interventions and the estimated risk reduction effects are shown in Table 4.

Table 4 The estimated effect of interventions on reduction of public health risks caused by *Salmonella* in sprouts. Data from (Ding and Fu, 2016)

Intervention	Median annual estimated loss of disability - adjusted life years (DALYs)
None	691,412
Seed treatment with 20,000 ppm of calcium hypochlorite	734
Microbiological sampling and testing of spent irrigation water (SIW)	4,856
Seed treatment + testing SIW	58
Seed treatment + microbiological testing of seeds, SIW and finished product	3.99

Sprout growers are required to take measures to prevent seed contamination, test spent irrigation water or in-process sprouts for certain pathogens and not release product unless negative, monitor the processing environment for *L. monocytogenes*, and take corrective actions if any tests are positive.

Juices are considered separate to fresh produce. FDA issued regulations in 2001, mandating wholesale fruit/vegetable juices to be produced under HACCP plans and juice has to be treated with a process achieving a 5 log₁₀ reduction in the most resistant pathogen (Danyluk et al., 2012). The pertinent pathogen is determined from epidemiological data and currently is NTS for citrus juice and STEC O157 and *Cryptosporidium* for apple juice. A recent orange juice outbreak was reported to be due to non-compliance with the regulation.

Pet food

NTS outbreaks have been associated with pet food in the USA and Canada (FDA, 2013a). Under the Federal Food, Drug, and Cosmetic (FD&C) Act (21 U.S.C. 342(a)(1), FDA considers pet food to be adulterated when contaminated with any NTS serotype due to the high likelihood of direct human contact with the pet food. Direct human contact animal feeds are deemed to be a lower human health risk and therefore considered adulterated when contaminated with NTS serotypes known to cause disease in the animal for which the feed is intended. Regulatory action is considered warranted in these products when NTS is present and the product will not receive a commercial heat step or equivalent process to inactivate NTS. Under the FSMA, pet food manufacturers with some exceptions are required to use GMPs.

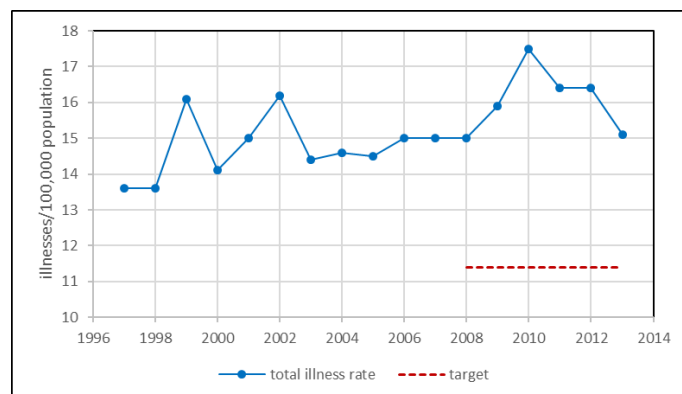
Evidence for success

Salmonellosis incidence

USA strategies to reduce NTS infections transmitted by food are driven by the goals set in the Healthy People 2020 targets. Agencies measure success in contributing to these goals using data from several sources such as illness surveillance, outbreak investigations, food attribution, epidemiological typing, verification testing programs and surveys.

In the Healthy People 2020 initiative the NTS illness baseline was 15.0 and the target 11.4 illnesses /100,000 population. Progress of infection rates since 1997 to 2013, compared with the target set in 2006-2008 are shown in Figure 3. The rate peaked in 2010 and while it has decreased to levels before the peak, the level is still significantly higher than the target. Overall this suggests NTS pathogen reduction measures need to be increased or further adapted if they are to make a further contribution to meeting the national public health objective. It is too early to assess some of the recent measures described here.

Figure 3 *Salmonella* infections commonly transmitted through food in the USA 1997-2013. The dashed red line is the target for Healthy People 2020 (ODPHP, 2016)



Outbreaks of salmonellosis

PulseNet and WGS have contributed to linking cases, foods and NTS sources in the recent outbreaks. The impact attributable to PulseNet on NTS illnesses between 1994-2009 was conservatively estimated to include: 266,522 total salmonellosis cases/yr. avoided from 2007-2008, 16,994 (90% CrI 3,750-33,021) cases avoided by recalls, illnesses indirectly attributable to industry reaction/responses for NTS averted numbered 9,096 (90% CI 8,504- 9,686) to 25,181 (90% CrI 20,747-29,595) and health cost savings were \$US1,792 (90% CrI \$US1,461- \$US2,295) (Scharff et al., 2015).

NTS illness notification data beyond 2013 were not found although there have been outbreak reports. Some outbreaks have been multistate (Table 5) for which the very large numbers of identified cases are a concern e.g. imported cucumbers in 2015/2016 with 907 cases and 6 deaths linked using PFGE and WGS over 40 states (CDC, 2016c). These outbreaks are presented to illustrate the broad range of foods and processing that need to be addressed for NTS as flagged by IFSAC.

Table 5 Multi-state outbreaks of salmonellosis in the USA, 2010-February, 2016, and implicated food vehicles. Data extracted for the CDC Foodborne Outbreak Online Database tool –Reports of selected *Salmonella* outbreak investigations, cited on 26/02/16 at <http://www.cdc.gov/salmonella/outbreaks.html>

Year	Chicken/ chicken dishes	Produce	Nuts/seeds/ spices and products	Meat/fish and products	Eggs	Other
2016 Jan- Mar		Alfalfa sprouts	Pistachios			Powdered supplement
2015	Frozen raw chicken meals (2)	Cucumbers (imp)	Raw sprouted nut butter spreads	Pork, frozen raw tuna		
2014	Chicken	Cucumbers, bean sprouts	Nut butter, organic sprouted chia powder, raw cashew cheese			
2013	Chicken (2)	Cucumbers (imp)	Tahini sesame paste (imp)	Ground beef		
2012		Mangoes (imp), cantaloupe	Peanut butter	Ground beef, raw scraped tuna product		Dry dog food
2011	Chicken livers broiled	Papayas (imp), alfalfa and spicy sprouts, cantaloupe (imp)	Pine nuts (imp)	Ground beef, ground turkey, turkey burgers		
2010		Alfalfa and spicy sprouts, Frozen mamey fruit pulp (imp?)	Black and red pepper on salami		Shell eggs (SE)	

Between 2012 and 2014 FSIS has reported not consistently meeting its All-Illness Measure agency performance target and this was due to the dynamics of STEC O157, NTS and *L. monocytogenes* in the collective target (FDA, 2015k). FSIS reported having moved from achieving 84% in 2012 to 99.5% in 2014 of its NTS illness target with reductions in salmonellosis numbers.

FSIS analysed 163 outbreaks (2007-2012) they investigated through linkage with FSIS regulated products as a measure of progress (Robertson et al., 2016). The aetiological agents were STEC (55%), NTS (34%), *L. monocytogenes* (7%) and *Campylobacter* (1%). The numbers of NTS outbreaks definitively linked with FSIS-regulated products decreased over the years although the number of NTS outbreak cases increased. Most NTS outbreaks were linked with commercial products sold raw, including raw beef 31 (55%), chicken 9 (22%), turkey 6 (15%) and pork 4 (10%) and also RTE products (11%), and a partially cooked product (e.g. stuffed chicken product). FSIS considers the general outbreak decrease could be related to success of the pathogen reduction and consumer education programs although also note other social and economic factors such as a decrease in the population's health care utilisation with the economic downturn, and resource contrasts in state and local health departments related to the recession and expenditure on the influenza A pandemic. The increase in the proportion of culture-confirmed cases and the benefit of molecular typing for enhancing detection of outbreaks was noted.

Among the 56 NTS outbreaks investigated by FSIS, the top serotypes were Typhimurium (21%), Enteritidis (14%) and Newport (14%) that are also top among human illnesses (Table 6). Three serotypes (Enteritidis, Heidelberg, and Hadar) closely associated with poultry, together were responsible for 30% of NTS outbreaks and 37% of NTS illnesses and this supports action on ongoing needs for NTS reduction in poultry.

Epidemiological typing

The CDC salmonellosis data includes all means of transmission although refers to them as “commonly transmitted by food”. Simple comparison of human serotypes alone with food isolates is speculative although this is reported by the agencies and in some cases may be useful by negative association. In human salmonellosis in 2013 Typhimurium decreased and Infantis and Javiana increased (see Serotypes and genotypes above). The more commonly isolated serotypes among FISIS regulated product classes in 2014 are shown in Table 6 (FSIS, 2015i).

Table 6 Top *Salmonella* serotypes in human illness (2014) and in FSIS regulated foods (2013). Data extracted from CDC (MMWR, 2015b) and FSIS (FSIS, 2015i)

Source	Top <i>Salmonella</i> serotypes
CDC Foodborne Diseases Active surveillance network, 2014	
Human illnesses	Enteritidis, Typhimurium, Newport, Javiana, I 4,[5],12:i:- Infantis
FSIS PR/HACCP verification sampling 2013	
Ground beef	Montevideo, Typhimurium, Meleagridis
Young broiler chickens	Kentucky, Enteritidis, Typhimurium
Ground chicken	Enteritidis, Kentucky, Infantis
Young turkey	Hadar, Reading, Muenchen, I 4,[5],12:i:-
Ground turkey	Reading, Muenchen, I 4,[5],12:i:-, Newport, Berta
FSIS 1995-2014	
Egg products	Heidelberg, Enteritidis, Typhimurium (including Typhimurium Copenhagen), Braenderup

Enteritidis is the top serotype in salmonellosis and an important risk factor for the SE infections in the rebound in the 2000s was eating chicken although eggs remain important (Discussed below). In 2013, SE was the top and second rating serotype in ground chicken and young broiler chickens, respectively, that would support the importance of measures to control NTS in poultry. The emergence of SE in chicken is shown in Figure 4. SE rates will provide a useful measure of success of interventions in future.

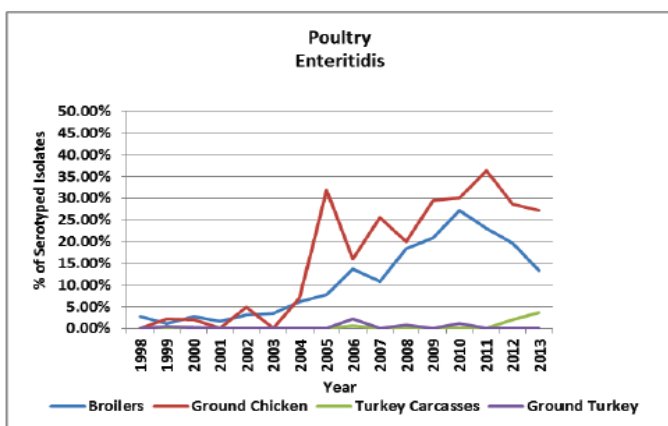


Figure 4 *Salmonella* Enteritidis in poultry in USDA, FSIS, PR/HACCP verification sampling by calendar year 1998-2005- “A “Set samples; 2006-2013 – all samples. Graph copied from (USDA, 2015)

Food contamination
Beef and poultry

The FSIS equates data for pathogen detection during verification testing of its regulated products with exposure of the population. In 2015, 0.05% of 13,187 samples of RTE meat and poultry samples were positive for NTS (USDA, 2015). The latest online available FSIS progress report of NTS testing in raw meat and poultry products is 1998-2014 (FSIS, 2015g). However, a shift in 2006 to risk-based establishment scheduling means prior years cannot be compared. Between 2006-2014 the cattle and hog product classes tested trended downward in the percent positives in the PR/HACCP verification testing program (Figure 5) and the proportion of sample sets meeting the PSs increased (Figure 6) and they are no longer tested indicating successes resulting from the PR:HACCP Rule. The performance of ground beef and poultry classes were insufficient and as described above these have been flagged for action (See *Salmonella* strategy, Annex 1).

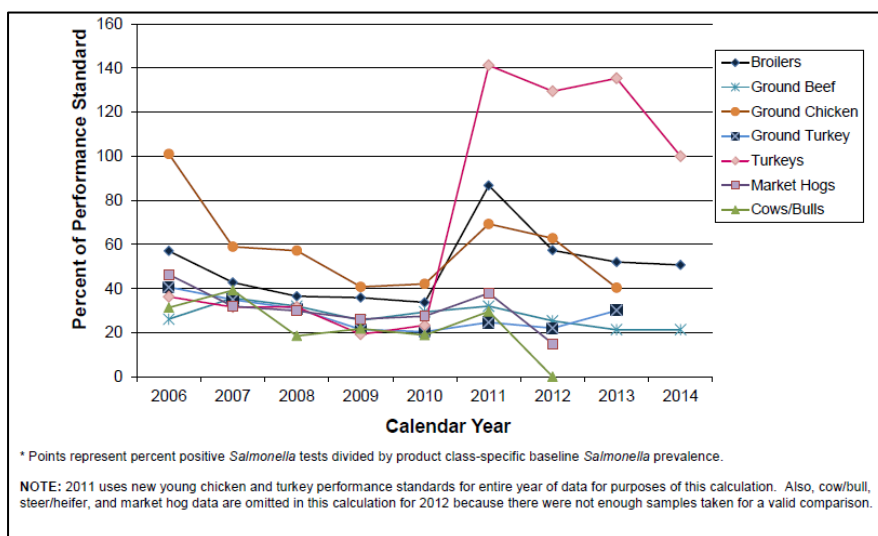


Figure 5 Comparison of percent positive NTS tests in the FSIS PR/HACCP verification testing program with baseline prevalence, by calendar year and product class, 2006-2014*. Graph copied from (USDA, 2015)

The ongoing improvement activities are works-in-progress and the impact in poultry and pork products will not be apparent until decisions and implementation are further advanced. FSIS tested poultry parts and comminuted products in 2015 and found no notable differences from the 2012 survey data (FSIS, 2016e).

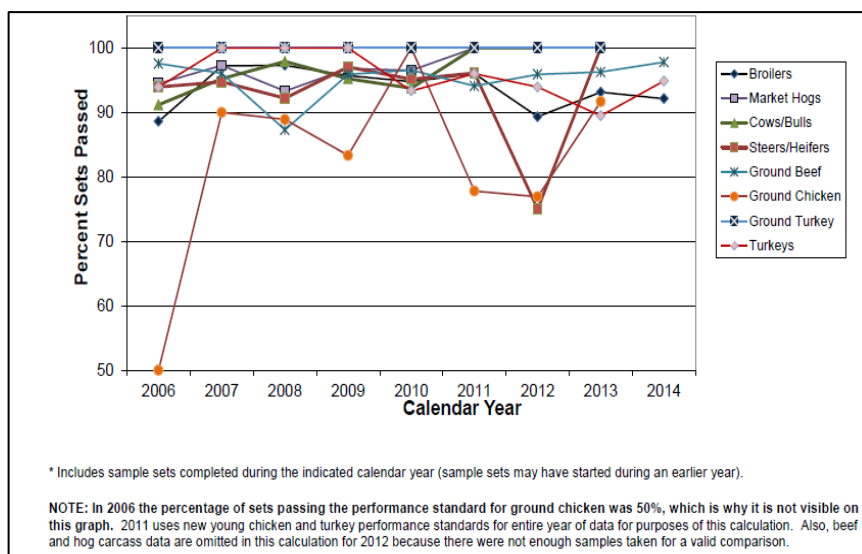


Figure 6 Overall percentages of sample sets meeting *Salmonella* performance standards by calendar year and product class, 2006-2014*. Graph copied from (USDA, 2015)

The USDA highlighted their achievements over the past 7 yr. (dated 2016) and are reproduced as follows (USDA, 2016):

- *Tougher standards have been set for NTS as well as new standards for Campylobacter on poultry carcasses which will reduce the bacteria on in poultry and that they expect will prevent up to 25,000 illnesses/yr.*
- *New standards have been set for NTS and Campylobacter in more commonly purchased chicken parts and this is expected to result in prevention of up to 25,000 illnesses/yr.*
- *The optional New Poultry Inspection System, an updated science-based inspection system that positions food safety inspectors throughout poultry facilities in a smarter way has been introduced. This system allows for FSIS inspectors to shift focus on routine quality assurance tasks to strategies that are proven to strengthen food safety. This can include more frequently removal of birds from the evisceration line for close food safety examinations, taking samples for testing, checking plant sanitation, verifying compliance with food safety plans, observing live birds for signs of disease or mistreatment, and ensuring plants are meeting all applicable regulations*
- *Labelling is required for beef products that have been mechanically tenderized including validated cooking instructions so that household consumers, hotels, restaurants and similar institutions have necessary information to safely cook these products.*
- *Traceability has been improved for ground beef including record keeping in retail.*
- *Engagement and education of consumer has been increased by use of social media and audience-appropriate messages. The Foodkeeper application for smartphones and tablets offers users valuable advice on food storage and safety for over 400 food and beverage items, including various types of baby food, dairy products and eggs, meat, poultry, produce, seafood, etc. The app is intended to help reduce food waste in addition to educating about proper food handling, and it has been downloaded over 90,000 times since it launched in April 2015. The app can be found at <http://www.foodsafety.gov/keep/foodkeeperapp/> (Accessed 08/03/16.*

Eggs

An epidemic of SE illnesses began in 1978 linked to shell eggs beginning in north-eastern USA then spreading country-wide by 1994 and as a result Enteritidis become the most common serotype and the focus of regulation (Chai et al., 2012). Voluntary interventions on farm, mandated pasteurization of egg products, consumer education, and requirements for refrigeration of eggs (SE is internalised in eggs) are believed to have been successful interventions resulting in the decline in rates of SE illnesses during the late 1990's. However, SE infections between 2003 to 2008 increased 44% compared with 1996-1999, particularly among the young ≤ 4 yr. This has prompted investigation and action by the 3 agencies. In a FoodNet case-control study in 2002-2003 it was found eating chicken outside the home (36%) and eating undercooked eggs (31%) were important risk factors for SE illnesses (Chai et al., 2012). International travellers contribute to the incidence but not the increase and other foods have been attributed e.g. sprouts, ground beef and Turkish pine nuts.

Shell eggs are not routinely tested by FDA and their models predict 1/20,000 or 0.005% shell eggs are contaminated with SE (Chai et al., 2012). Under the Egg Rule sampling scheme there is a 95% probability of detection of a positive egg from a flock producing contaminated eggs. In 2010, one of the largest USA outbreaks, a multi-state SE outbreak linked with shell eggs, occurred involving a total of 3,578 recorded illnesses and likely many more (CDC, 2010). Non-compliance with the Egg Rule was

found with extensive contamination detected in the farm environment including egg wash water and hundreds of millions of eggs were recalled. This was a reminder that SE control has to be rigorous and ongoing and of the impact of large scale production and distribution networks.

In FSIS regulated egg products that are required to be pasteurised, the total NTS percent positive from 2008 to 2014 was 0.19% and has followed a downward trend, Figure 7 (FSIS, 2015e).

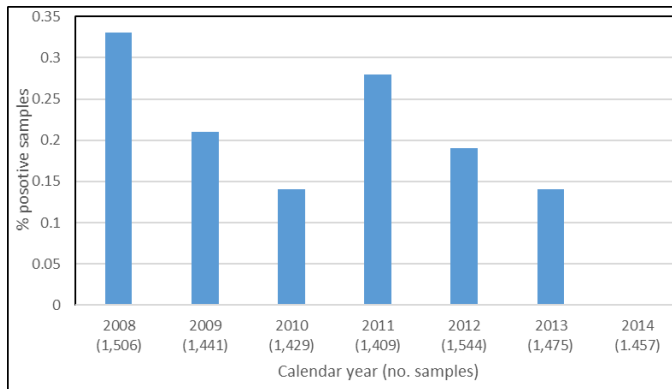


Figure 7 *Salmonella* in pasteurised egg products calendar years 2008 – 2014. Data from USDA-FSIS (FSIS, 2015e)

The results from 2008 onward cannot be compared with results from previous years because of the change in reporting and similarly are not to be compared with FDA data. From 1995-2014 of 94 NTS egg product isolates serotyped from 30,957

egg samples, Heidelberg (24) and Enteritidis (19) were the most common serotypes followed by Typhimurium (10, including Typhimurium Copenhagen) and Braenderup (10).

From 2000 the rate of SE among NTS isolates from FSIS verification testing in broilers and ground chicken (Figure 4) increased significantly while a mean of 0.06% pasteurised egg products in FSIS tests yielded SE (Chai et al., 2012). The use of molecular and WGS typing has been successful in investigating changing SE epidemiology. SE PFGE types from illnesses, foods and chickens have been compared and the common chicken isolates (70-80% isolates) were also common in half the human isolates providing evidence the rebound in SE illness is linked with chicken meat.

NTS remain an issue in eggs with both SE as well as other serotypes considered of concern e.g. Heidelberg. The FDA has in 2013 established cooperative agreements with external research groups with commercial research facilities to investigate the contamination of shell eggs including (FDA, 2013b):

- routes of vertical and horizontal NTS (all serotypes) transmission and the effects of physical feed characteristics and housing,
- how commercially utilized disinfection protocols affect horizontal transmission of NTS in alternative versus traditionally housed layer hens,
- observation of behaviour of other NTS serotypes present which may pose a potential health risk to consumers.

Produce

The produce industry has responded to the occurrence of illness related to produce with voluntary food safety measures; however, outbreaks and recalls have continued linked to both local and imported produce prompting regulatory action (Allan, 2013). The preventive controls and standards for the produce industry in the FSMA is a new initiative, covering the entire industry, strengthening controls and success of their approach remains to be determined. Produce is highly diverse and the FSMA requires a focus on products the FDA deems of highest risk. The scope of the Act includes fresh fruit and vegetables, mushrooms, sprouts, and peanuts and tree nuts, and the FDA will prioritise regulations based on evidence of illnesses and foodborne illness attribution.

The determination of risk may present particular challenges. Allan (2013) commented on challenges he believed should be considered in defining risk categories for commodities in the produce industry

based on outbreak/illness data including “*the interplay of number, extent and severity of outbreaks, the timeframes for baseline periods, the effect of consumption/exposure on illness data and the effect of identifying (or not) a food vehicle on illness data*” (Allan, 2013). He further commented on considerations required when defining risk categories for commodities by positive sampling data such as the ‘*availability of contamination data by commodity is highly variable, and contamination testing is driven, in part, by perceived risk; outbreak ranking is not static and could require moving commodities from one risk category to another, based on new data; and, operations with multiple commodities in different risk categories, but with similar practices and conditions, could be subject to multiple standards and control regimes at a single farm*’. Additional challenges included “*risk associated with a given commodity varies depending upon practices employed (e.g., regional practices and conditions) and practices may change over time for a given commodity*”.

Campylobacter

Public health and economic burden

The term *Campylobacter* is used although it is recognised *C. jejuni* is the most common serotype causing illness in the USA and more than one species can cause illness.

Campylobacteriosis is not a notifiable disease in the USA although it can be reported through the NNDSS and FoodNet. *Campylobacter* was ranked as the fourth most common cause of foodborne (9%) illness in the USA in 2011, and was estimated to cause 845,024 (337,031–1,611,083, 90% CrI) illnesses, 8,463 (4,300–15,227, 90% CI) hospitalisations and 76 (0–332, 90% CI) deaths/yr. (Scallan et al., 2011). Eighty percent of the infections were estimated as foodborne. The economic burden of *Campylobacter* has been estimated to rank 5th among the foodborne pathogens costing \$US1,608.4 million/yr. (Hoffman, 2015).

In 2014, FoodNet reported among pathogens transmitted commonly through food, 6,486 (33%) culture-confirmed *Campylobacter* illnesses or 13.45 incidence/100,000 population, 1,080 (17%) hospitalisations and 11 (0.2%) deaths and 0.6% outbreaks were due to *Campylobacter*. Among the *Campylobacter* reports, 1,070 were not included as 553 (52%) were culture-independent, and 517 (48%) were culture-negative (MMWR, 2015b). Culture-confirmed *Campylobacter* illnesses had increased 13% (CI = 5%–21%) since 2006-2008 (Figure 1).

Antimicrobial resistance among *Campylobacter* isolates is an increasing concern in the USA (USDA/CDC, 2013). Ciprofloxacin and azithromycin are antimicrobials used to treat campylobacteriosis and CDC reports resistance to ciprofloxacin in almost 25% and to azithromycin in about 2% of isolates tested. FDA withdrew approval for use of fluoroquinolones in poultry in 2001 and 2005. *Campylobacter* are rated as a “serious” threat among AMR concerns in the USA by the CDC and FDA.

Campylobacter infections are sporadic and do not commonly cause outbreaks and the epidemiological features vary between both illness groups (Altecruse et al., 1999). CDC and collaborating agencies and researchers have investigated cases to provide evidence for establishing pathogen reduction measures. Sporadic illness numbers were higher in summer and outbreaks higher in temperate seasons, and illnesses occurred more often among infants and young adults. Risk factors varied among population groups and regions. Food related risk factors included, in particular, handling raw poultry and eating undercooked poultry, and also drinking raw milk or milk from bird-pecked bottles, eating barbecued pork and sausages. In Arizona where Hispanics have a higher rate of illness, risk factors included eating cantaloupe, handling raw poultry, and eating queso fresco (Pogreba-Brown et al., 2016). High illness rates among neonates and infants have been attributed, in part, to lower immune status and to the low threshold for seeking medical care for infants, and among young adult males, it is thought to reflect poor food-handling practices in a population new to preparing their own meals.

Food attribution

IFSAC reported among outbreaks between 1998-2012, 33% outbreaks and 17% illness for *Campylobacter* occurred between 2008-2012 (IFSAC, 2015). Two food categories accounted for the majority of estimated illnesses, dairy (66%; 57-74%, 90% CrI) and chicken (8%; 5-12%, 90% CrI) although there was a wide array of food categories recorded (land and aquatic animals, plants) and with high credibility intervals. Dairy outbreaks were mainly linked to raw fluid milk or cheese produced from raw milk (e.g. unpasteurised queso fresco). IFSAC authors pointed out studies of sporadic cases find low attribution to dairy products in comparison with these findings and as the general population does not regularly consume raw dairy products, extrapolation of outbreak analyses to the broader population is problematic. On the other hand, the incidents of illness linked to raw milk and milk products should be considered among the small proportion of the USA population that are exposed by choosing to consume these products.

The incidence of infections follows a strong seasonal pattern and is higher in summer (Williams et al., 2015). USA federal and state agencies investigated human illnesses and contamination of raw poultry products simultaneously and supported a hypothesis of a weak seasonal summer increase in poultry prevalence though concentrations decreased slightly. They concluded poultry may be an important food source; however, it was not the likely driver of the seasonal patterns of human illness.

Risk management and regulatory approach

The Healthy People 2020 initiative requires a 33% reduction of *Campylobacter* illnesses commonly transmitted by foods with a target incidence of 8.5 cases per 100,000 population compared with a baseline of 12.7 cases/100,000 population reported in 2006-2008. The key food groups for action identified by IFSAC were dairy and poultry and these are addressed by both the FDA and USDA together with state and municipal authorities.

Dairy

Milk

The FSMA now mandates implementation of preventive controls for all human foods (FDA, 2015h). Farms are not required to register under the FSMA unless they conduct manufacturing/processing activities beyond those included in traditional farm practices of production of fluid milk and cream.

The FDA Grade "A" Pasteurised Milk Ordinance (PMO) 2011 Revision has been the recommended legal requirement for adoption by States, Counties and Municipalities, for the purpose of facilitating the shipment and acceptance of milk and milk products of high sanitary quality in inter- and intra-state commerce (FDA, 2011a). Previously, the FDA's role was advisory and did not have legal jurisdiction except in interstate carriers and milk and milk products in interstate commerce that means intra-state sales are regulated independently by States. When implemented, the PMO requires inspection and auditing of dairy farms, plants, transport and transfer stations and HACCP programs in milk plants, receiving and transfer stations in order to acquire a permit. The PMO is being revised to incorporate the requirements of the FSMA.

It is a violation under federal law, to sell raw milk packaged for consumer use across state borders. Federal Code 21 CFR Sec. 1240.61 mandates pasteurisation and specifies process criteria (FDA, 2015a). The PMO defines levels for somatic cells and standard plate counts in milk. FDA may consider all dairy products adulterated and prepared, packed, or held under insanitary conditions when nontoxicogenic *E. coli* is found at levels >10 MPN/gm in two or more subsamples or > 100 MPN/gm in one or more subsamples (FDA, 2010).

In 2008 there were 29 States that allowed some type of on- or off-farm raw milk sale and cow share or leasing arrangements providing consumer access to raw milk, although few allowed sale in retail stores (Oliver et al., 2009). Some States incorporate requirements in their legislations to minimise

pathogen risks: improved hygiene in collection and distribution or labelling on containers or at the point of sale advising of the risk.

Cheese

The FSMA mandates processors will have written preventive food safety measures in place and control of environmental pathogens in the processing environment (FDA, 2015h). There are food standards of identity for cheeses and related cheese products, 21 CFR 133 (FDA, 2015b). The standards specify process and product criteria for cheese categories based on the predicted behaviour of pathogens. When pathogens are likely to survive the processing and if pasteurisation is not specified, an aging period of 60 days at a temperature of not less than 35°F (1.6°C) is specified. There has been investigation into the effectiveness of this criterion particularly with regards to survival of STEC O157 and *Listeria* that are able to survive and grow in some cheese varieties during these maturation conditions. As for raw fluid milk, States vary in their implementation of regulations and on sales of raw milk cheese and cheese products.

Mexican-style soft cheese such as queso fresco are particularly risky when made with raw milk as they are high moisture, high pH cheeses made with no starter cultures. They are popular in ethnic groups and can be simply and cheaply made in illegal so called “bathtub” conditions evading regulatory attention and are sold by unregistered street vendors and in markets.

The FDA uses *E. coli* levels (See under Milk above) as a measure of unsanitary conditions in a cheese processing plant. The agency is currently re-evaluating the need for a microbial specification for domestic and imported cheeses within the framework of the FSMA that requires food producers have in place HACCP-based control measures (FDA, 2016a).

Poultry

FSIS regulations for *Campylobacter* and poultry and recent changes have been described in the preceding *Salmonella* section. In the 2012 survey used as evidence of contamination of raw poultry products, *Campylobacter* were more prevalent after carcasses were fabricated although the rates of positive samples were much lower than for NTS in parts and comminuted products (Figure 2). To contribute to the Healthy People 2020 goal, a 33% reduction in campylobacteriosis, FSIS has proposed a matching goal for illness reduction associated with chicken parts and comminuted chicken (FSIS, 2015b). Turkey was found to have a much lower prevalence of contamination and the target is 19% for comminuted turkey (Figure 2). To assist industry in meeting the regulatory requirements FSIS provides guidance in combination with NTS as they are common hazards to be controlled in these products (Annex 2).

The performance standards for raw poultry are shown in Table 3. The sampling sets for the FSIS PSs are based on sufficient samples /day over a time period sufficient to demonstrate sustainability of control (FSIS, 2015b). This sampling plan limits inclusion of farms by size (e.g. min. 20,000 birds) as farms with low numbers were expected to slaughter intermittently over the year and as it would take more than a year to collect statistically valid sampling numbers this was not an option.

Evidence for success

Campylobacteriosis incidence

The incidence of culture-confirmed campylobacteriosis cases has increased since the 2006-2008 baseline of 12.7 cases/100,000 population and remains well above the target of 8.5 cases/100,000 population as shown in Figure 8. The impact of culture-independent diagnostic testing on surveillance is listed by CDC as a challenge to be resolved in their surveillance programs (Cited 16/03/16 at <http://www.cdc.gov/foodsafety/diseases/campylobacter/technical.html>).

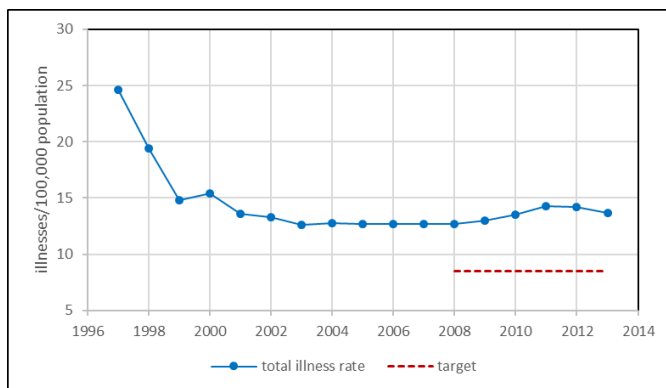


Figure 8 *Campylobacter* infections commonly transmitted through food in the USA 1997-2013. The dashed red line is the target for Healthy People 2020 (ODPHP, 2016)

Outbreaks of campylobacteriosis

Most cases are sporadic and not recognised as clusters or outbreaks and efforts to increase submission of isolates to PulseNet and molecular typing is expected to improve epidemiological investigations. Using the CDC FOOD Tool (<http://wwwn.cdc.gov/foodborneoutbreaks/>) the number of campylobacteriosis outbreaks decreased in 2009 and has increased sharply since. Outbreaks linked to chicken increased from 1/year in 2011 to 6/yr. in 2014. These observations underpin the responsive action of FSIS on PSs for all poultry in 2016. Inadequately cooked poultry livers have been implicated more recently with 3 linked to chicken liver in 2014. The success of the new control measures and PSs for poultry remains to be determined.

Transmission of campylobacteriosis via dairy products remains an uncontrolled public health concern, particularly those made from raw milk both where raw milk sale is legal and illegal. CDC reported outbreaks linked with unpasteurised milk increased from 30 in 2007-2009 to 51 in 2010-2012 (Mungai et al., 2015). *Campylobacter* caused 77% of the outbreaks, the number of outbreaks had nearly doubled between these periods and the average per year was 4 fold higher. CDC analysed 90 cheese outbreaks reported between 1998-2011 and found 49% and 42% due to pasteurised and unpasteurised milk cheeses respectively (Gould et al., 2014).

Food contamination

Poultry

See also Evidence for success with NTS. Campylobacteriosis has been of lesser importance than the other pathogens reviewed in the USA. There are changes in progress in regulations for raw poultry in response to the more recent increased public health burden and the impact will not be apparent until they are fully implemented.

FSIS introduced a verification testing program for young chicken and turkey carcasses in 2011 (FSIS, 2015g). The aggregated figures for 2011-2014 for *Campylobacter* were 7.0% for young chickens and 2.5% for turkeys. The baseline prevalence for *Campylobacter* on poultry carcasses for years 2011 - 2014 were:

- Young chickens: 2011 9.3%, 2012 7.0%, 2013 7.2%, 2014 6.0%
- Turkeys carcasses: 2011 4.2%, 2012 2.3%, 2013 2.4%, 2014 2.0%

The prevalence has been decreasing for chicken and remained stable for turkeys after a drop in 2011-2012. FSIS tested poultry parts and comminuted products in 2015 and found no notable differences from the 2012 survey data, evidence used in their efforts for improvement (FSIS, 2016e).

Milk

In 88% of campylobacteriosis outbreaks linked with raw milk, the product was purchased in States where its sale was legal and the increase in outbreaks paralleled a decline in the number of states where sale of unpasteurised milk was illegal (Mungai et al., 2015). Raw milk-associated outbreaks were 2.2 times higher in states with legal raw milks sales. Sales across borders of states with legal and illegal unpasteurised milk sales also occurs. The legal sale of unpasteurised milk in many USA States

and the increase in this trend is a major ongoing challenge and banning these sales nationally is a political issue. Mungai et al (2015) recommended active and ongoing education of State and local legislators and of consumers of the dangers and of the need for strengthening of law enforcement prohibiting these sales in individual states.

Cheese

The major contributing factors for recent cheese outbreaks appear to have been post-processing contamination of pasteurised cheeses, raw milk cheeses produced in States allowing their sale, or imported and illegally produced products (Gould et al., 2014). CDC reported NTS, *Listeria* and also *Campylobacter* were a concern in unpasteurised queso fresco or other Mexican style cheeses that were frequently imported from Mexico or produced locally and/or sold illegally.

FDA surveillance sampling shows that the vast majority of domestic and imported raw milk cheeses were meeting the established *E. coli* criteria and on this basis they are revising requirements as described above. The California Department of Public Health provided a consumer health warning in March, 2016, advising of the dangers of consuming illegally manufactured Mexican-style soft cheese following a number of NTS infections linked with the products (Report available at <https://www.cdph.ca.gov/Pages/NR16-012.aspx>, cited 19/03/16).

The American Cheese Society surveyed artisan, specialty, and farmstead cheesemakers in the USA and Canada in 2012 (ACS, 2012). Of 211 producers participating, ~35% produced raw milk products exclusively, 59% produced some raw milk cheese, some both milk types. Reports of food safety related practices were: 48% had a HACCP plan in place, 61% documented GMPs, 48% conducted independent pathogen testing, 46% reported audits or FDA inspections and 56% reported having a product recall and/or crisis management plan. The cheesemakers associations are working with regulators to improve the implementation rate of food safety measures among the raw milk cheese processors to reduce risks.

Listeria

Public health and economic burden

Listeriosis became notifiable in the USA in 2001. *L. monocytogenes* has been estimated (2011) to cause 1,591 (90% CrI, 557–3,161) domestically acquired foodborne illnesses/yr., 1,455 (90% CrI, 521–3,018) hospitalisations and 255 (90% CrI, 0–733) deaths (Scallan et al., 2011). Listeriosis was the 3rd leading cause of deaths (19%) and 99% cases were estimated to be foodborne, the exception being neonates. In 2014, FoodNet reported 118 cases (0.24 cases/100,000 population) and 11% outbreaks were caused by *L. monocytogenes* (MMWR, 2015b). The Healthy People Initiative 2020 target for listeriosis is 0.2 cases/100,000 population and the 2014 rate, 0.24 cases /100,000 population is above this (Figure 1). In the *Listeria* Initiative, an advanced surveillance program has been introduced where (see following) in 2014, 675 cases (98% invasive) were reported from 47 States and the District of Columbia, 96 (15%) were pregnancy-related, the mean patient age was 70 yr. (0-95yr), 83% were hospitalised, and 23% died. The economic burden of listeriosis in the USA is estimated at \$US2,834.4 million/yr. which is third, comprising 18% of the total cost after salmonellosis (24%) and toxoplasmosis (21%) (Hoffman, 2015). This rating is because of the high mortality rate associated with listeriosis.

Enhanced surveillance

The CDC in collaboration with the other agencies has established special programs for listeriosis surveillance due to the severity of the illness. It is included in the CDC national case-based surveillance where information is collected on individual cases and not just outbreak cases. The *Listeria* Initiative was established in 2005 and is an advanced surveillance system aimed to speed identifications, investigations and public health preventive action (CDC, 2016a). The *Listeria* Initiative requests laboratories forward all clinical isolates of *L. monocytogenes* to PulseNet for subtyping. Further, the

Listeria Whole Genome Sequencing Project (WGS) began in 2013 and is a collaborative project of the agencies and external groups.

Serotypes and genotypes

Three *L. monocytogenes* serotypes (1/2a, 1/2b, and 4b) cause most (95%) human illnesses. In the past, in outbreaks linked with deli meats, hot dogs and soft cheeses, serotypes 4b was most common together with epidemic clones I, II and Ia (based on multi-virulence locus sequence typing, MVLST). More recent produce outbreaks have been caused by serotype 1/2a and 1/2b with multiple molecular types in an outbreak and including novel epidemic clones (Garner and Kathariou, 2016).

Food attribution

IFSAC reported to the federal agencies that between 1998-2012, 50% of outbreaks and 60% of illnesses caused by *L. monocytogenes* occurred in the last 5 yr. (IFSAC, 2015). Two food groups were attributed to 81% of illnesses, fruits (50%; 90% CrI, 5-77%) and dairy products (31%; 90% CrI, 12064%). The credible intervals for this pathogen were the widest among those analysed and thought to be due to the comparatively small number of outbreaks in the study period. In earlier years RTE products of animal, seafood and dairy origin were more common, while recently, produce and novel foods have been implicated also. Many produce outbreaks have been multi-state. The cantaloupe outbreak in 2011 was exceptional and described as the largest listeriosis or pathogen outbreak in the USA, involving 28 states, 147 cases, 33 deaths and one foetal loss (Garner and Kathariou, 2016). Other unusual fruit-related outbreaks have been linked with stone fruit and caramel apples (caramel coated toffee apples). In 2015 CDC investigated suspected or confirmed outbreaks linked with: chicken, pork, sprouts, cheese, ice cream, nut butter, cucumbers and raw frozen tuna and currently frozen corn and peas are suspected to be linked with cases linked retrospective by genotyping (CDC, Cited 05/05/16 at <http://www.cdc.gov/listeria/outbreaks/frozen-vegetables-05-16/index.html>).

Risk management and regulatory approach

The target for listeriosis reduction in the Healthy People 2020 Initiative is 0.2 cases/100,000 population and the priority food groups are fruits and dairy products.

RTE foods

Fruits and dairy are priority food groups although RTE foods in general remain important. These foods are regulated by both the FDA and USDA FSIS and some USA food manufacturers may produce both FDA and USDA regulated foods at the same establishment.

Following early outbreaks of listeriosis the FSIS and FDA as risk managers conducted a risk assessment in 2001, *Quantitative Assessment of the Relative Risk to Public Health from Foodborne Listeria monocytogenes Among Selected Categories of Ready-to-Eat Foods* that indicated those RTE foods that support growth of *L. monocytogenes* posed the highest risk and those intrinsically or extrinsically or, processed to alter characteristics, posed the least (FSIS, 2012a). Highest priority foods were deli meats, pasteurized fluid milk, high fat and other dairy products, and un-reheated frankfurters.

For FSIS regulated-products, deli meats were their highest risk foods and they conducted a further risk assessment for these products (FSIS, 2012a). A combination of interventions in deli meats exposed to the environment after the lethality treatment were identified to have the greatest impact on lowering the risk of illness or death and these became the basis of the regulation 9 CFR 430.4, Control of *Listeria monocytogenes* (*Lm*) in Post-Lethality Exposed Ready-to-Eat (RTE) Products, also referred to as The *Listeria* Rule.

Under the *Listeria* Rule, post-lethality exposed RTE products are considered adulterated if they contain *L. monocytogenes* or come in direct contact with a food contact surface that is contaminated with *L. monocytogenes*. Essentially the Rule identifies *L. monocytogenes* as a hazard in these products that has to be controlled either by implementation of a HACCP plan, and/or control of the environment

using a SSOPs or another program. Use of validated treatments can be claimed on product labels (Annex 5).

FSIS regulatory verification testing includes testing for *L. monocytogenes* or *Listeria* in product and the environment using an FSIS developed algorithm. Samples are collected under several plans: random collection from establishments producing RTE products (25g), post-lethality-exposed products and contact surfaces collected based on establishment risk, non-contact environmental surface swabs, and brine and water samples (FSIS, 2016c).

FDA regulated food groups posing high risk in the risk assessment were broader e.g. dairy, seafood and produce. These foods are now regulated under the FSMA requiring HACCP-based preventive programs (FDA, 2015h). Together with FDA requirements for GMPs in manufacturing, packing and holding food, guidance documents were provided for industry in 2008 on control of *L. monocytogenes* in refrigerated and frozen RTE foods. Essentially these include formulating refrigerated RTE foods to prevent growth, destroying viable cells, controlling ingredients, worker training, building design, sanitation and monitoring, corrective action and record keeping (FDA, 2008). Guidance documents present FDA thinking on best practice and have no legal standing.

Retail sector and RTE foods

The retail sector is regulated through the FDA Food Code 2013 (FDA, 2013c). The FSIS provides additional guidance for best practice for use alongside the FDA Food Code by the retailers of meat and poultry products and for their compliance investigators (FSIS, 2015a). A joint agency comparative risk assessment for *L. monocytogenes* in RTE meat and poultry deli meats was conducted in 2010 to update regulation and the guidelines (FSIS, 2015a). Deli meats sliced and packaged at retail were found responsible for 83% listeriosis cases. The key findings of the risk assessment, from experience with current regulations, and external consultations, resulted in an update of the retail guidelines in 2015 and the key interventions and predicted public health impact from the risk assessment are summarised in Annex 4. Notable changes from 2014 were related to prevention of biofilms with specific recommendations that food processing equipment should be disassembled (every 4 hours, Food Code 2013) and scrubbed to prevent biofilm formation, and sanitisers rotated to prevent development of *Listeria* resistance.

The FSIS apparently believes more should be done at retail and at a public meeting in March 2016 will discuss how FSIS could better ensure retail control of *L. monocytogenes* (Cited 20/03/16 in USDA notices at <http://www.fsis.usda.gov/wps/wcm/connect/c98df493-56ff-4052-b33f-1e680c703503/2016-0005.pdf?MOD=AJPERES>). Discussion will include whether FSIS should rely on regulation, the Food Code, or some other means to effect control and whether there are sources of information FSIS has not identified that should be considered.

Dairy

The regulations covering milk and cheeses and also the concern for variable regulation among States on the sale of raw milk and milk products have been reviewed in the preceding *Campylobacter* section.

The potential for survival or growth of *Listeria* in cheeses and the effectiveness of the 60-day aging requirement has been questioned and debated. The FDA collaborated with Health Canada in developing a model to evaluate factors impacting on public health risks from consumption of soft-ripened cheeses (FDA, 2015l). A finding was that the 60-day aging period for soft-ripened cheeses may increase the risk of listeriosis by allowing more time for any *L. monocytogenes* present to multiply rather than decrease as the cheeses age. When the risk effects of interventions applied in raw milk and pasteurised milk cheese processing were compared (using North American data), interventions that led to lower mean risk levels of raw milk cheese included testing of every lot of soft-ripened cheese made from raw milk and removing positive lots from the supply chain, and applying a process that results in a 6 log₁₀ reduction of the pathogen in the milk.

Post-processing contamination is addressed at the processors and at retail; however, the illegal industry evades all requirements. The FSMA includes requirements for environmental monitoring and finished product testing as verification activities as appropriate to the agent, the food and the control measures (FDA, 2015h). Therefore, testing for environmental monitoring for *Listeria* spp. is recommended for certain RTE dairy products, e.g., facilities making soft cheeses exposed to the environment. The approach to retail food handling is described in the section above and some flow over would occur between products with FSIS and FDA requirements.

The FDA is considering further measures and has requested comments, scientific data and information for their consideration on intervention measures effecting the presence of bacterial pathogens in cheeses manufactured from unpasteurized milk that closed on November 2015. FDA Notice, FDA-2015-N-2596-000, cited 10/03/16 at <https://www.regulations.gov/#!documentDetail;D=FDA-2015-N-2596-0001>).

Produce

The approaches to regulation of domestic and imported produce by the FDA and the FSMA has been described in the *Salmonella* section and in Annex 3. The FDA estimates it will prevent about 332,00 illnesses per year, including listeriosis, by introduction of the Produce Safety Rule. The FDA is required to prioritise the implementation for specific fruits and vegetables that are raw agricultural commodities based on known food safety risks that may include history and severity of outbreaks (FDA, 2015h). The Rule does not cover farms that have an average annual value of produce sold during the previous 3-year period of \$US 25,000 or less with some qualifiers (FDA, 2015j).

Specific requirements for *L. monocytogenes* were included in the rule for sprouts to address environmental contamination where testing of the growing, harvesting, packing and holding environment for the presence of *Listeria* spp. or *L. monocytogenes* is required (FDA, 2015f). For biological soil amendments, the use of raw manure is still being assessed to develop risk management strategies, while standards have been established for pathogen levels in stabilized compost and recommendation have been made of scientifically valid production methods (Annex 3). Guidance documents and compliance training are to be produced together with other agencies and industry.

Consumer education

Each of the agencies has developed extensive educational material for consumers on the dangers of *Listeria* in foods addressing high risk consumer groups and highlighting risky foods. There are numerous government agency websites providing factual information, video clips recording testimonies from cases, and links to regulations and compliance. An example is the CDC “Food safety and raw milk” at <http://www.cdc.gov/foodsafety/rawmilk/raw-milk-index.html>. The FDA uses 3 icons for handling RTE foods: chill, use food as soon as possible, and clean (Cited 23/03/16 at <http://www.fda.gov/Food/ResourcesForYou/Consumers/ucm079667.htm>).

Date labelling

Date labelling to inform on safe shelf life of food is not generally required in federal law except for infant formula and there is no uniform or universally accepted system although about 20 States require dating of some foods (FSIS, 2015d). “Open dating” is found on perishable foods (meat, poultry, eggs and dairy products) and “closed dates” on shelf-stable foods. There are various types of date labels (sell-by, best if used by (or before), use-by and closed or coded dates) and these are quality or manufacturer indicators. The FSIS points out that a food can be mishandled by the consumer even if within a use by date and not be safe. Consumer guides for home storage and handling are provided on agency websites e.g. FSIS <http://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/food-labeling/food-product-dating/food-product-dating>. Foodkeeper is an app for use on mobile devices and is a guide on how to use food at peak quality; however, it not a safety indicator. See <http://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/featured-campaign0>.

Evidence for success

Listeriosis incidence and outbreaks

The incidence of listeriosis decreased between 1997 and 2000 and has remained unchanged since although the rate remains above the Health People Initiative 2020 target (Figure 9). Using the CDC FOOD Tool, listeriosis outbreaks have increased from 2009 from less than 5/yr. to 9 in 2014. Examples from recent years are shown below. It can be seen the key fruit and dairy groups remain significant, some causing large and/or multi-state outbreaks and this drives regulatory action.

- 2016 - packaged salads, raw milk
- 2015 – soft cheese, ice cream,
- 2014 – caramel apples, sprouts, fresh curd cheese, Hispanic style cheese,
- 2013 – soft cheese (some including truffles),
- 2012 – imported ricotta salata cheese
- 2011 – cantaloupe.

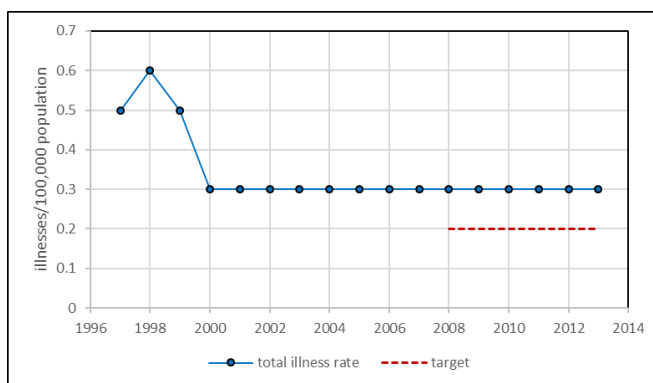


Figure 9 *Listeria monocytogenes* infections commonly transmitted through food, USA, 1997-2013 and Healthy People 2020 target (red dotted line). Source (ODPHP, 2016).

Enhanced surveillance

The enhanced surveillance, molecular subtyping and whole WGS of *Listeria* isolates has been reported by the agencies to be highly successful in identifying clusters and outbreaks of listeriosis, identification of food sources, removal of products from the marketplace and identification of environmental contamination sources. Cases geographically and temporally dispersed that might have been considered sporadic have been associated and linked with widely distributed food products and the contamination sources identified (CDC, 2016b; FDA, 2015d). For example, cases of listeriosis in 2 states in 2014 were later linked with raw milk from a single farm in 2016 as a result of WGS by the FDA.

Scharff et al (2016) conservatively estimated the impacts attributable to PulseNet on illnesses due to *L. monocytogenes* based on data from 1994-2009 and concluded 56 listeriosis cases/yr. were avoided, 27 (90% CrI, -38, 92) to 151 (90% CrI, 46-256), illnesses indirectly attributable to industry reaction/responses were averted between 2007-2008 and health costs of \$US156,019 (90% CrI, \$US81,003- \$US254,934) were saved (Scharff et al., 2015).

Food contamination

RTE meat and poultry

Among FSIS assisted investigations of 89 outbreaks linked with FSIS regulated products between 2007-2012 (Robertson et al., 2016), *L. monocytogenes* was the causative agent of 7% outbreaks and 38% of deaths.

In 2015, 0.34 % of each of 3,277 random and 9,479 risk-based samples (25g) of RTE meat and poultry products were positive for *L. monocytogenes* (FSIS, 2016b). This rate has progressively decreased from 4.61% in 1990 and has ranged from 0.18% – 0.39% since 2007. However, this rate was higher for 537 composited samples (5x 25g) of which 1.3% were positive. Other results included: contact surfaces 0.6% of 5,325, and non-contact environmental surfaces 9.14% of 536 and these have not changed

notably since 2012 when testing began. FSIS issued a best practices guideline to help delis and other retailers to decrease the potential for *L. monocytogenes* contamination. A pilot project to assess retailer's voluntary adoption of the guideline recommendations will be conducted 2016 to explore further action.

Dairy

Raw milk continues to be a food safety issue with legal sales in many USA states although NTS, O157 STEC and *Campylobacter* have caused the greatest number of outbreaks (See *Campylobacter*, Evidence for success, Milk). The 2016 listeriosis outbreak was linked with raw chocolate milk served to elderly patients at high risk (CDC, 2016b).

United Kingdom

The United Kingdom (UK) is made up of several countries, England, Scotland, Wales and Northern Ireland and is a sovereign state of Europe and a member of the European Union (EU). There are both commonalities (e.g. adoption and implementation of some laws) and differences (surveillance sources) between the UK countries.

Evidence of health and economic burdens of foodborne illness

The burden of UK-acquired foodborne illness and the attribution of these illnesses to food commodities was undertaken 2011-2012 based on data from 2009 and these data have been used to inform risk management strategies for reduction of foodborne pathogens to 2015 (O'Brien, 2014). It was estimated about 1 million cases of foodborne illness occur each year, 20,000 were hospitalised, 500 died and the cost was nearly £1.5 billion (UKFSA, 2011).

Campylobacter was estimated from 2009 data to be the most common microbial foodborne pathogen causing 280,400 (182,503-435,693, 95% CrI) cases/yr. although it caused a small proportion of hospitalisations (rate 1.1%) and about 100 deaths (O'Brien, 2014). NTS were estimated to cause 33,130 (8,178-128,195, 95% CrI) foodborne illnesses/yr.; however, NTS caused the highest rate of hospitalisations for any single foodborne pathogen with a rate of 3.5% among all cases and 7.6% in outbreak cases. The estimate for listeriosis was 183 (161-217, 95% CrI) cases.

The trend of total notifications of laboratory-confirmed cases of NTS and *Campylobacter* infections from 2005-2014 is shown in Figure 10 (UKGov, 2015). The annual population growth rate in the UK in the 2000's was 0.64%. Listeriosis case reports increased and decreased over time (Figure 14).

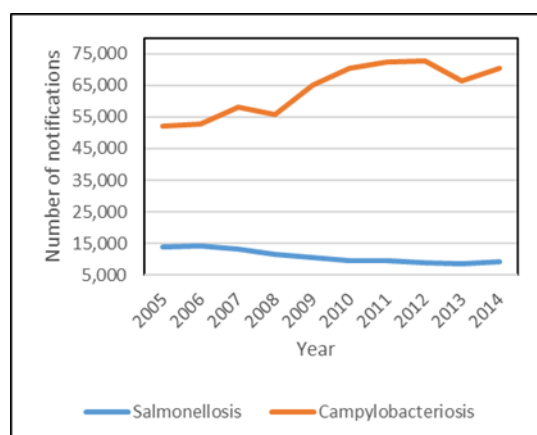


Figure 10 Notifications of laboratory-confirmed cases of salmonellosis and campylobacteriosis in the UK 2005-2014 (UKGov, 2015)

Food Attribution

From the 2009 study, there were 308 salmonellosis outbreaks of which 86.4% were foodborne; 44 campylobacteriosis outbreaks with 70.5% foodborne and 2 foodborne listeriosis outbreaks among already hospitalised patients (O'Brien, 2014). In a food attribution study of O'Brien (2014) for the UK FSA, poultry was the most common food linked with foodborne illnesses (O'Brien, 2014). In 2013, poultry was the food identified in 32% foodborne outbreaks due to all microbial agents and particularly *Campylobacter* spp., followed by red meat (23%), and seafood (16%). Other important foods were eggs and produce. The importance of eggs as a transmission vehicle has decreased since 2000.

UK agencies and food safety

The Food Standards Agency (FSA) promotes the microbiological safety of food through the food chain, is responsible for the strategy for reducing foodborne illness, and provides guidance on food safety for producers, retailers, caterers and the general public. The FSA is responsible for meat inspection in England, Scotland and Wales. (See <http://www.food.gov.uk/science/microbiology> (Cited 09/04/16).

The Department for Environment Food & Rural Affairs (DEFRA) is responsible for safeguarding the environment, supporting the food and farming industry and rural economy, and has input into on farm measures in a through chain approach. The UK is a member country of the CAC and along with other members has played a keen role in development of deliberations from the CCFH on food safety management and applies the Codex principles in its food safety risk management.

Foodborne Disease Strategies

The FSA has developed 5 yr. Foodborne Disease Strategies since its inception in 2000 and these have included pathogen reduction strategies using 2000 data as their baseline (UKFSA, 2011). In 2001-2005 the FSA Strategy was broad-based and commodity specific with a target to reduce the incidence of UK foodborne illness by 20%. Key efforts included sector-specific measures to reduce food contamination, wider promotion of HACCP, and improved kitchen hygiene by means of the Food Hygiene Campaign (UKFSA, 2011). There was considerable success by 2005 with a 19.2% reduction in foodborne illness. While the target was met, the UK FSA was not able to determine which interventions implemented had the greatest impact on the observed reductions. The burden and cost of foodborne illness remained high and the renewed strategy for 2005-2010 following the same lines resulted in little significant change in foodborne illness notifications.

The 2010-2015 strategy was more focused using a targeted approach to controlling foodborne pathogens versus a commodities-based approach and required a defined risk management program. A Food Chain Analysis was used to identify key pathogens and to develop risk management programs that would focus effort on identifying intervention points where contamination levels and human illness could be most effectively reduced. The pathogens identified to offer the greatest benefit to public health through reduction measures and controls were *Campylobacter* as it caused most illnesses, *L. monocytogenes* as it caused the most deaths, and viruses as they were an emerging concern (UKFSA, 2011). NTS, STEC O157 and *Clostridium perfringens* were the other key pathogens. The risk management approach followed the risk management framework of the CCFH and NZ uses the same framework. The proposed 2015-2020 Strategy is being reviewed currently and the FSA pledges to put consumers first in all their future activities (UKFSA, 2016b).

Food law and regulation

The Food Standards Act 1999 is the overarching framework of all legislation in Britain (UKGov, 1990) with equivalents in other UK countries. The General Food Law Regulation (EC) 178/2002 provides the

general principles of food safety including the requirement for safe food to be placed on the market, food labelling, traceability, recall of unsafe food and management of imports and exports. The Food Safety and Hygiene (England) Regulations provide for the enforcement of regulations.

The production, processing, distribution, retail, packaging and labelling of food stuffs in the UK are governed by multiple laws and regulations with codes of practice and guidance for local authorities and industry that enforce and implement them. These have bearing on control of the pathogens in this review to varying degrees. Much of the detailed legislation and food standards in the UK in 2016 originate in the EU Regulations and these can be accessed via EUR-Lex at <http://eur-lex.europa.eu/collection/eu-law.html> (Cited 08/04/16). Regulation (EC) 852/2004 covers the hygiene of foodstuffs and 853/2004 the specific hygiene rules for food of animal origin. The regulations incorporate risk analysis principles with a strong science base and the use of food safety metrics with regards to workings of the CCFH. The use of HACCP principles is recommended in food safety management although not yet in primary production where guides to good practice should apply. Over time regulations on feed, animal health, and general hygiene have not been adequate in providing the required level of control for foodborne zoonoses such as NTS and *Campylobacter* infections and specific requirements for controls based on targets for pathogen reduction detailed in National Control Programmes have been established. Listeriosis is approached separately.

Training. Food business operators are required by law, to ensure that food handlers in their business receive appropriate supervision and instruction/training in food hygiene appropriate to their work activity that should enable them to handle food safely (See <https://www.food.gov.uk/business-industry/food-hygiene>. Cited 09/04/16).

Food hygiene rating scheme. Businesses that make or prepare foods are inspected by enforcement officers. Those that supply food to the public may be covered by the Food Hygiene Rating Scheme (England, Wales) and receive a hygiene rating or by the Food Hygiene Information Scheme (Scotland) and receive a “pass” or “improvement required” rating. The results are available to the public on line and the business receives a sticker/certificate that can be voluntarily displayed. The UK FSA’s evaluations of the scheme from 2011-2014 indicate the rate of compliance among business increased significantly in England although not significantly in Scotland. Although the overall aim is to lower foodborne illness it was not possible to relate implementation of the scheme with foodborne illness benefits (<https://www.food.gov.uk/news-updates/news/2015/13770/fhrs-evaluation-findings-published>. Cited 09/04/16). In the FSA Science, Evidence and Information Strategy 2015-2020, it is proposed to integrate data from the scheme with other platforms (e.g. Yelp, TripAdvisor and Google) to maximise the visibility and the use of these data and their impact on the awareness and behaviour of consumers and businesses. It is also proposed to use studies of “mental models” for inspectors to gain improved consistency in ratings.

The Food Hygiene Campaign is an adjunct to pathogen-specific work and promotes safe food handling and preparation in the home and catering sector which are settings where foodborne illness incidents often occur (UKFSA, 2011). In the 2010-2015 Strategy it was planned to refresh this campaign to encourage behaviour change in groups such as school age children who are the building blocks for food safety both inside and outside the home and through the promotion of Food Safety Week and similar activity.

Non-typhoidal *Salmonella*

The approach to NTS control varies between EU countries although they commonly include controls from farm to consumer. In poultry, this has been a top down control approach for control of

“regulated” serotypes in flocks using an elimination strategy by eradicating infected flocks at the top of the pyramid by mandatory slaughtering. The following review is focused mainly on the UK approach.

Public health and economic burden

Salmonellosis incidence is significantly lower than campylobacteriosis (Figure 10) although it is associated with a higher hospitalisation rate in outbreaks (O'Brien, 2014). More than 80% cases were estimated to be attributable to foodborne transmission. Infections and outbreaks were in epidemic proportion in the 1990's and fell significantly over the next decade. In 2014 there were 9,121 notifications of laboratory confirmed cases and this was an increase from 8,461 in 2013 due to an increase in notifications in England and Wales (UKGov, 2015).

Serotypes

NTS serotypes currently of key public health significance are Typhimurium and Enteritidis and monophasic Typhimurium incidence is increasing. EU Legislation and testing requirements for food of animal origin have moved to a risk based focus for control of NTS foodborne infections by targeting “regulated” serotypes. These types are identified based on health data on the top serotypes among notified human infections rather than on all NTS serotypes (EFSA, 2014). SE infections that included predominantly SE PT4 but also other PTs, peaked in the UK in 1988-1998 outnumbering Typhimurium infections and the decline was associated with specific control measures (Lane et al., 2014). The decline in PT 4 has coincided with other PTs assuming a larger proportion of SE isolates and similarly other serotypes have increased in importance with the decline in SE.

Serotypes differ among livestock species linked with foodborne zoonotic illnesses in the EU e.g. SE, Typhimurium and Infantis in poultry. Monophasic 4,[5]12:i:- have been increasing in animals e.g. pigs, cattle, sheep and also poultry meat, and pork and beef have been linked with outbreaks (EFSA, 2014). Serotype Dublin is the most common NTS in cattle followed by Typhimurium and its variants.

Food attribution

Eggs, poultry and pork have been most commonly attributed to NTS infections (Pires et al., 2014). The foods attributed during the SE epidemic mainly included raw egg dishes and to a lesser extent chicken. In 2014, there were 12 outbreaks caused by NTS attributed to poultry meat (2), red meat (4) crustaceans and shellfish (1), composite foods (1), other foods (2), and unknown sources (2).

Risk management and regulatory approach

Eggs

The approach in EU directives for the control of NTS in eggs is to enforce minimisation of infection in breeder and layer flocks. Member countries may have their own additional regulations for NTS reduction in poultry that have had varying degrees of success. In 2008 the EC adopted 2 regulations aimed to reduce and control the prevalence of NTS in poultry and eggs following assessment of risks:

1. Targets were set for EU member states for the reduction of NTS prevalence in laying hens by a specific percentage each year (beginning in 2008) proportional to their baseline levels which was expected to reduce the levels in eggs (EC, 2006b);
2. Rules were set on the methods used to control NTS in poultry, including mandatory vaccination for member states with prevalences $\geq 10\%$ (EC, 2006a).

Trade ban options on eggs from infected flocks was also considered for commencement in 2010 where eggs from infected flocks would be banned for sale as table eggs, Class A, and would have to undergo a sterilisation procedure if processed for egg products. The EC Regulation stated that antimicrobials should not be used as part of national control programs unless under limited circumstances due to the risks of AMR development and as it makes detection of NTS difficult. The use of live NTS vaccines

is also prohibited unless the manufacturer can provide a method to distinguish the vaccine strains from wild strains.

Annual percentage reduction targets for NTS in laying hens were developed to reach an ultimate prevalence of $\leq 2\%$. As the prevalence varied in EU member states the reductions were progressive depending on the prevalence in the preceding year as follows:

- 10% reduction if the prevalence of NTS in the preceding year was $< 10\%$;
- 20% reduction if the prevalence of NTS in the preceding year was 10-19%;
- 30% reduction if the prevalence of NTS in the preceding year was 20-39%;
- 40% reduction if the prevalence of NTS in the preceding year was $> 40\%$;

Egg production is regulated under (EC) 852/2004 and (EC) 853/2004 (UKFSA, 2009a). According to the guides for inspection the following are the main points and measures for control.

- Birds and housing – maintain hygiene in housing (or outdoor environment) and equipment and disinfect as necessary; apply measures to ensure cleanliness of laying hens;
- Feed and water – control feed contamination (milled and free range feed) and use potable or clean water, assess risks of water for free range hens;
- Pests and other livestock – prevent from causing contamination of flocks;
- Inspection, disposal and veterinary inputs – prevent introduction of infectious diseases, exposure to chemical hazards, correct use of veterinary medicines;
- Egg collection and storage – maintain hygiene and disinfection as required; eggs kept clean and dry;
- Systems and transport – containers, crates and vehicles to be kept clean and disinfected as necessary; eggs protected from physical damage, kept clean and dry, out of direct sunshine;
- Egg storage and packing materials – hygienic packaging, eggs protected as during transport;
- Hygiene control and personnel – staff in good health and trained for their tasks and food handled hygienically;
- Record keeping - all relevant records kept.

Vaccines with manufacturer authorisation can be used although not mandated in the UK (EFSA, 2014).

Legislation (EC) 853/2004 requires shell eggs to be clean, kept dry and free from cracks. Cracked eggs can be used for manufacturing where they must be used as soon as possible. Manufacturing product must be labelled with storage temperature and use-by date. Untreated liquid egg must be labelled “non-pasteurised egg products – to be treated at place of destination” and with date and hour of breaking.

Accredited voluntary assurance schemes in the UK such as the Lion Code of Practice for Commercial Layers are commonly adopted. These are Codes of Practice that support the Legislation and are claimed to be more stringent (Lion, 2013). Nearly 90% of UK eggs are now produced under this scheme that covers the entire egg production chain, requires flock vaccination, production hygiene and feed control, microbiological testing, temperature and time control of storage of eggs, traceability, and consumer advice via retailers. The key elements of the Lion Code are shown in Annex 6.

During the SE PT4 epidemic there were active campaigns providing advice to consumers, especially vulnerable populations, to avoid eating raw or uncooked food with raw egg ingredients and to cook eggs so that the yolks and whites were solid. (O'Brien, 2013). Caterers/restaurateurs were encouraged to use pasteurised eggs in uncooked products, to consider eggs and egg dishes short shelf-life products, and to store eggs at $< 8^{\circ}\text{C}$ throughout the production chain.

Monitoring and process verification

All flocks on UK farms with >350 laying hens not accredited to any assurance scheme must comply with the National Control Programme for *Salmonella* in Laying Flocks implemented in 2008. Eggs originating from flocks infected with SE or S. Typhimurium cannot be sent for human consumption unless treated in a manner that will guarantee the elimination of NTS (DEFRA, 2007). Exempt are flocks where all production is for private domestic use, and, if the holding has fewer than 350 hens and supplies direct to the consumer or via local retailers.

The *Salmonella* National Control Programmes are required for each of chicken breeders, layers and broilers, and turkeys (EC, 2006b). Provided are rules for monitoring flocks, measures to be taken if positive, rules for monitoring NTS at processing and slaughter, and in feed, and for overall performance targets for NTS reduction. The sampling strategies are provided Annex 7. All UK isolates from birds or their feed or environment must be reported and submitted to reference laboratories.

The respective UK *Salmonella* National Control Programmes have the following targets and requirements.

The breeding flock sector must ensure no more than 1% of adult breeding flocks with > 250 birds remain positive for regulated NTS serotypes annually. The regulated serotypes in the EU in 2013 were Enteritidis, Typhimurium, Virchow, Hadar, Infantis, and monophasic Typhimurium variants. Layer breeding flocks positive for serotypes Enteritidis or Typhimurium (including monophasic strains) are held under official control and are compulsorily slaughtered and eggs from the hatchery destroyed. Approved cleaning, disinfection and follow up negative test samples from the empty house are required for permission to resume production. For the other serotypes, a control plan for the eradication of the infection has to be applied under supervision of government and veterinary experts. For broiler parent breeding flocks, alternatives to slaughter are offered under the Zoonoses Order.

The target for layer flocks is set for no more than 2% prevalence of regulated serotypes which in the EU includes the 2 most common serotypes, Enteritidis and Typhimurium, and any laying flock found to be infected is placed under official control. The eggs from positive flocks or flocks of unknown NTS status can no longer be used as table eggs, Class A, and must undergo a heat process to eliminate the risk of NTS contamination. Operators that challenge result have an option to test 4,000 eggs or the internal organs of 300 birds or 5 faecal and 2 dust samples per flock.

Meat

Red meat

There are several EU Regulations (EC) 852/2004 (Hygiene rules) and (EC) 853/2004 (Hygiene rules for food of animal origin) and domestic regulations that aim to reduce the level of foodborne pathogens on fresh meat and poultry (UKFSA, 2015). There is no statutory National Control Programme for NTS in cattle. All laboratory isolates must be reported and sent to reference laboratories and most data is from diagnostic samples. Official control of slaughter establishments is enforced by the FSA in Britain and the equivalent in N. Ireland. Other meat activity (mincing, preparations, mechanical separation, processing, cold storage and re-wrapping) come under local authorities. Codes of Practice for good farm practices are provided and frequently implemented though government recognized farm assurance schemes. NTS vaccination for serotypes Dublin and Typhimurium can be used on a voluntary basis (EFSA, 2014).

There are some specific pre-slaughter requirements for animals and birds:

- The Clean Livestock Policy was introduced in response to STEC O157 concerns in 1996 and is used to categorise cattle and sheep at ante-mortem inspection based on visible cleanliness and dryness. Only top rated category animals are allowed to proceed to slaughter.
- Food Chain Information has to be supplied by business operators (farmers or producers) to slaughterhouses in advance of livestock arriving for slaughter unless inspection occurs on farm. This should be supplied in time to allow the HACCP managers at the slaughterhouse to make decisions on acceptance of livestock or to make special processing arrangements e.g. scheduling positive lots, requiring additional dressing procedures or reducing line speed. For poultry, information is required on membership of an assurance scheme and for flock NTS test results under the *Salmonella* National Control Programme although not time off feed.

Slaughterhouse and meat processing food business operators are required to implement and maintain hygiene procedures based on HACCP principles and the pre-requisites and it is a legal requirement to ensure staff are trained appropriately for their responsibilities. The 3 pathogens reviewed in this report are identified as hazards to be controlled in HACCP plans in meat and meat product production. The details are available in the Meat Industry Guide (UKFSA, 2015).

The highest bacterial risk currently presented by the ruminant food chain in the UK is linked with STEC O157 that has been a cause of severe illnesses and deaths. It could be expected that some measures taken for STEC O157 will have flow over to NTS control. Control options identified include reducing contamination and spread among animals on farm and the use of decontamination during slaughter such as steaming carcasses.

Visible contamination is usually removed by trimming. The EU Regulation does not allow the use of any substance other than potable water to remove contamination from products of animal origin unless approved. The EFSA undertakes a risk assessment before considering approval of decontamination processes. Lactic acid has been approved and not mandated for use under certain conditions e.g. only for bovine carcasses or parts thereof, by spraying or misting of 2-5% lactic acid solution at temperatures up to 55°C and under controlled and verifiable conditions within a HACCP plan.

A recently emerged issue is the production of smoked skin-on sheep meat that is popular in some ethnic communities and produced in unlicensed premises. The EU and UK Regulation does not allow skin-on sheep meat and in the FSA Strategy 2015-2020 Delivery Plan the development of hygienic and safe production practices will be investigated (UKFSA, 2016c).

Pork

NTS in pigs as a source reservoir for human infection has been of concern in the EU resulting in increasing attention to reduction measures (EFSA, 2014).

In the UK, with the reduction in the risk of NTS in poultry and eggs, the relative attribution rate of pork and pork products was predicted to rise from 10-15% even though the prevalence rates were unchanged. EC *Salmonella* National Control Programmes require herds of breeding and slaughter pigs leaving for slaughter or carcasses at the slaughterhouse to be tested for NTS serotypes of public health significance. There had been no statutory *Salmonella* National Control Programme for NTS in pigs in the UK although a target was set in the 2005-2010 FSA Strategy to reduce the incidence of NTS positives in pigs by 50% (EFSA, 2014). Codes of Good Practice developed with industry are available as for red meat. All NTS isolates have to be notified and about 90% of NTS notifications from pigs are from subsidised diagnostic samples resulting from disease diagnosis and investigations. A national survey of caecal contents and pre-chill pig carcasses at slaughterhouses using a herd based approach representing 80% of national production was conducted in 2013. The prevalence of caecal carriage

ranged from 11.3 - 46.8% and carcass contamination ranged from 0 - 21%. The most common serotypes isolated were monophasic Typhimurium variants followed by Typhimurium, Derby and Bovismorbificans. The detection rates were significantly higher than the EU and this provided evidence supporting the need for investigation of further control measures.

Poultry meat

The UK National Control Programme for NTS in broilers had a target to reduce broiler flock prevalence of SE and *S. Typhimurium* and variants to <1% by end of 2011. This has been achieved and given the requirements for breeders described above under *Eggs* it is expected that day old chicks placed on farms are SE and *S. Typhimurium* free.

DEFRA provided a Code of Practice to assist flock owners in their standard management practices. The keys to best practice for disease control in poultry expected to achieve the required status in the National Control Programmes include broadly, biosecurity, NTS free incoming chicks, NTS control in feed and water, disinfection, pest control, cleaning, disinfection and pest control at depopulation, monitoring and good farm management and transport practices which is not dissimilar to layer flocks. The use of antimicrobials as a control measure is prohibited. The UK has voluntary assurance programs that specify best practice and these are taken up by about 95% of chicken meat producers in the UK and the level of detection under these systems is very low. The biosecurity standards were amended as part of the *Campylobacter* Strategy and the amendments are described under that section following.

Monitoring and process verification for meat, poultry

In the UK *Salmonella* National Control Programme, the broiler flock sectors must ensure that no more than 1% of flocks are positive for NTS of greatest human health significance that in the EU in 2013 included Enteritidis or Typhimurium (including monophasic strains). If these regulated serotypes are detected official samples are collected from the next flock and other flocks on the holding and if these are positive a restriction notice is served under the Zoonoses Order, including supervised cleaning and disinfection and further sampling. If these samples are positive, birds can only be moved off the site under licence to the slaughterhouse and on further testing. The requirements specified for broiler flocks include testing (2 pairs boot swabs or drag swabs) within the 3 weeks' period before slaughter and it is important to know the flock status before the first birds are slaughtered and before depopulation. Official samples are randomly collected from 10% holdings with >5,000 birds or after a flock is positive and conditions apply for derogation not to sample (DEFRA, 2008). The testing results are provided to the slaughterhouse in the Food Chain Information to allow HACCP managers to consider appropriate control measures to avoid cross-contamination.

Regulation (EC) 2073/2005 on Microbiological Criteria for food of animal origin includes both food safety and process hygiene criteria that are provided in Annex 7 (UKFSA, 2015). The food safety criteria include testing for NTS and *L. monocytogenes* in raw and RTE foods as appropriate. Process hygiene criteria include indicator tests for APC, Enterobacteriaceae and *E. coli* in combinations relevant to the foods. NTS criteria sets for carcasses are considered as process criteria as it is considered NTS can include strains that may and may not be human pathogens. Specific serotypes of key public health importance are set in some cases e.g. poultry meat. Food business operators are required to analyse the trends in their test results (UKFSA, 2015). Authorities verify compliance by auditing HACCP-based procedures and test records.

Raw minced meat, and meat preparations from species other than poultry (e.g. burgers and sausages) for which there is an NTS food safety criterion must be clearly labelled by the manufacturer for retail sale to inform the consumer of the need for cooking prior to consumption (UKFSA, 2015). Cooking

information includes times and temperatures of cooking; however, internal temperatures are not recommended as it is considered this is not easily measured. Best practice recommendations include safe storage (e.g. temperature and separate raw and cooked food) and handling (wash hands and utensil etc. after handling raw meat) advice. Mechanically separated meat lots that fail an NTS food safety criterion must be used in manufactured heat treated product.

Dairy

There are EU regulations for general hygiene provisions in primary production of milk including hygienic production and criteria for raw milk and the UK FSA provides guidance on the production of milk (UKFSA, 2013b). EU regulations state criteria for raw milk should establish “trigger” values that if exceeded should prompt corrective action and reporting, and not prevention of sale. The following microbiological criteria are specified in the UK for raw milk including that intended for consumption untreated, based on a rolling geometric average over 2 months with 2 samples/month (UKFSA, 2013b). Somatic cell counts apply but are not included here.

- Cows’ milk: APC (30°C) ≤ 100,000 cfu/ml,
- Other species milk: APC ≤ 1,500,000 cfu/ml, and for milk products, APC ≤ 500,000 cfu/ml.

Raw milk intended for human consumption has the following standards:

- Plate count at 30°C (cfu per ml) < 20,000 cfu/ml and coliforms (cfu per ml) < 100 cfu/ml.
- Raw drinking milk for sale must be labelled in England with ‘*This milk has not been heat-treated and may therefore contain organisms harmful to health*’ and in Wales ‘*The Food Standards Agency strongly advises that it should not be consumed by children, pregnant women, older people or those who are unwell or have chronic illness*’ is added.

Raw milk cheese has to be labelled on the packaging as being 'made with raw milk' at point of sale. See more at: http://www.food.gov.uk/enforcement/codes-of-practice/food-law-practice-guidance-england-2015/food-law-practice-guidance-england-2015/food-law-practice-guidance-england-2015/7-4-matters-relating-to-raw-milk-and-dairy-products#_ftn1.

No NTS were detected in surveillance of retail cheeses made from raw or low-heat treated cows’ (24) and goats’ (43) milk, butter (5), cream (4), ice-cream (272), and milk powders (10) in 2013 (EFSA, 2014).

General foodstuffs

The Regulations (EC) No 2072/2005 lays down food safety criteria for NTS for 18 groups of foodstuffs including minced meat and meat preparations, mechanically separated meat, egg products, ice cream and dried infant formulae. These define the acceptability of the foods as placed on the market and throughout their shelf life.

Evidence for success

Salmonellosis incidence and outbreaks

Salmonellosis notifications in the UK increased in the mid-1980s with the SE epidemic (EFSA, 2014). The number of NTS infections has since declined significantly and this is considered due to successful control measures targeting SE PT4 including the use of flock vaccination (Figure 11).

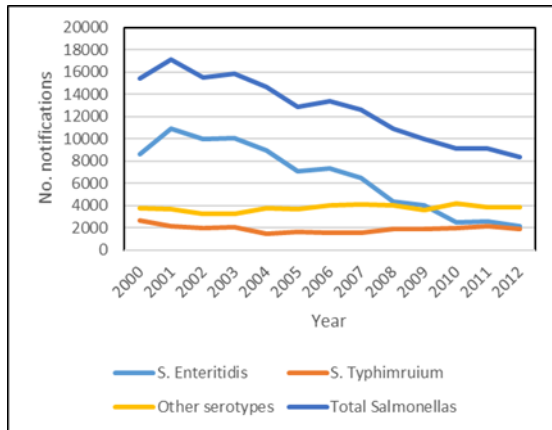


Figure 11 Non-typhoidal *Salmonella* serotypes among all isolates typed by Public Health England 2000-2012 (SR from Public Health England cited 07/04/18 at

<https://www.gov.uk/government/publications/salmonella-by-serotype/salmonella-by-serotype-2000-to-2010>)

While overall NTS human cases in the UK dropped about 19% between 2009 and 2013, it has increased slightly in 2014 (UKGov, 2015). In Figure 11, the serotype dynamic that does not remain stable can be seen in England where the fall in infections in 2009-2010 was associated with a decrease in SE while others serotypes increased proportionately by 16% and Typhimurium increased slightly.

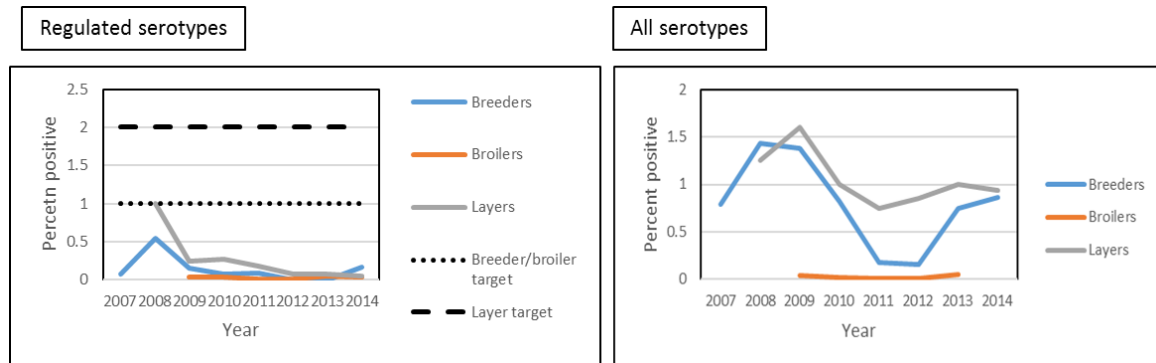
Food and livestock contamination

Eggs and poultry

The SE epidemic linked with eggs and poultry was influential in UK NTS control measures in 1989 with the expanding of the Zoonoses Order requiring the reporting of NTS from poultry as well as mammals etc. This produced little effect on prevalence of NTS in poultry flocks over the next 4 yr. Legislation was changed and the Breeding Flocks and Hatcheries Order 1993 was introduced requiring testing of all breeding flocks and mandatory slaughter of positive flocks and the situation improved. Since the beginning of the *Salmonella* National Control Programme, the prevalence of regulated NTS serotypes in the breeder, broiler and layer sectors in annual regulatory sampling has remained well below the required national and EU prevalence targets of 1%, 1% and 2%, respectively (DEFRA, 2015) (Figure 12). However, the prevalence of total NTS serotypes is dynamic in animals and birds as it is in human infections.

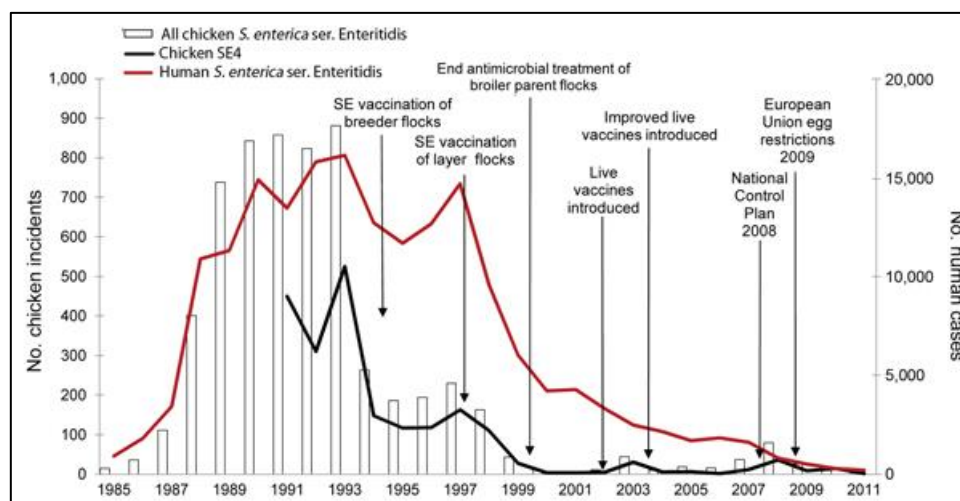
All serotypes. In 2014 in Great Britain, there was 138.8 million chickens, an increase of 4.2% since 2014 and these included approximately 40.6 million breeding and laying hens and 97.8 million broiler chickens (DEFRA, 2015). In 2014, 34 different serotypes were isolated from chickens. Enteritidis has decreased from representing 33.1% isolates in 2008 to 1.2% in 2014. Typhimurium has also decreased although the monophasic serotype first detected in chickens in Great Britain in 2010 has increased. Mbandaka has been the most common serotypes for several years and the others in the top 5 in 2014 were Senftenberg, 13,23:i:-, Kedougou and Montevideo. The prevalence of NTS of all serotypes has been most variable among breeder and broiler flocks (Figure 12). Serotype 13,23:i:- has recently emerged and was the most common type in breeding flocks in 2014. It may have originated from feed production facilities. In layer flocks, there is a differentiation with age as NTS detection rates in in-rear (immature) flocks has declined since 2008 while among adult flocks the rates have been fairly stable for about 5 yr.

Figure 12 Prevalence of all and regulated serotypes of *Salmonella* in breeder, broiler and layer poultry flocks in the United Kingdom 2007 to 2014(DEFRA, 2015). Targets are shown by the dotted lines.



Serotype Enteritidis. The interventions for SE in poultry have been very successful overall. The progress against trends in human notifications and chicken incidents is shown in Figure 13. A 2 stage decline of SE occurred in chickens and the first was a rapid decline of 70% about the time of the introduction of voluntary vaccination of breeder flocks and hygiene programs in 1993. This was followed by a plateau believed linked with vaccination uptake (Lane et al., 2014). The trend in laboratory reports of human infections was only effected to a limited degree at this time; however, the number of chicken-related outbreaks declined sharply from 1994. The second stage of SE decline in chickens in 1997 followed extension of the vaccination program to layer flocks, enhanced farm hygiene and management with uptake of farm assurance schemes. Human notifications began to sharply decline in 1997 as did egg-related outbreaks. Further developments have been introduced with the use of live poultry vaccines and regulatory activity and the levels of SE has remained low.

Figure 13 Trends in reporting of incidents of *Salmonella enterica* serotype Enteritidis in chickens and human laboratory notifications of salmonellosis in Great Britain, 1985-2011 and interventions (Lane et al., 2014). Reproduction permitted by CDC with acknowledgement of source (Lane et al., 2014).



During the epidemic, 1992-2011, the role of eggs and egg dishes and chicken meat changed. Among 471 SE PT4 outbreaks with known transmission routes during the epidemic, the most common risks were consumption of chicken meat (16%) and raw egg dishes (41%). The proportion attributable to chicken fell from 16% (331/192) in 1992-1993 to 10% (4/39) in 1994. During the epidemic stage eggs were associated with 79% (159/201) SE PT4 outbreaks, lightly cooked desserts accounted for 40%

(80/201) and lightly cooked/uncooked sauces for 11% (22/201) of these. The proportion of outbreaks linked with desserts declined to 17% (16/95) in the following 13yr. with decline in the epidemic while those linked with sauces remained about the same. It was hypothesised that the restaurant sector adopted the advice to use pasteurised eggs in raw egg-based desserts lowering the SE risk.

In contrast, SE PT4 outbreaks linked with simple eggs dishes (boiled, scrambled, fried rice etc.) commonly eaten in the home and outside assumed an increased proportion of outbreaks from 12% (6/51) to 67% (33/49) as the epidemic declined. Simple egg based dishes such as fried rice in Chinese restaurants were a concern where imported shell eggs were used together with poor hygiene in the food service sector (Lane et al., 2014). In the 2009 data used in setting the 2010-2015 Strategy, egg-related cases commonly associated with NTS accounted for only 5% cases although 30% of hospitalisations (O'Brien, 2014). Currently there is a public consultation on a draft report to the FSA that indicates the risk from salmonellosis in UK shell eggs produced under the Lion Code is very low. It is therefore considered that eggs produced under this or equivalent assurance schemes can now be served raw or lightly cooked to those in the most vulnerable groups, including pregnant women, the young and elderly (Cited 14/04/16 at <https://www.food.gov.uk/committee/acmsf/news-updates/news/2016/14899/fsa-launches-consultation-on-eggs-report>).

Red meat and meat and poultry products. In the 2013 surveillance report, no NTS was detected in 25g samples of cooked RTE broiler (133) and turkey (9) meat products at retail (EFSA, 2014). Red meat and products have been a concern for STEC O157 transmission. In the FSA Strategy 2015-2020 investigation of technological and scientific barriers to delivering safe food in meat plants will be undertaken. This may be driven by need for further control of STEC O157 although it will have flow on benefits to NTS control (UKFSA, 2016c).

Sweden

The Swedish NTS control programme began in 1961 and Swedish red and white meat and eggs are now virtually NTS free (EFSA, 2013b). The incidence rate of human NTS infections is about 8.3 cases/100,000 population. The food attribution trend has been changing from large meat-related outbreaks to smaller vegetable-related outbreaks and imported foods and travellers are important sources. While the Swedish program is highly effective it is costly and the Government is now considering ways it could be modernised, setting goals with defined targets along the food chains. The following summarises the program to date.

All poultry flocks are tested under a voluntary preventive program and all positive flocks are euthanized regardless of NTS serotype, results notified, and the source is investigated. Vaccines are not used. On farm measures are overseen by veterinarians and include all-in and all-out production of broilers, hygiene standards and barriers, incoming stock only from others affiliated with the program and only heat treated feed is allowed. Affiliated members receive greater compensation in the event a flock is infected and mandatorily slaughtered. Broilers are tested 2 weeks before slaughter and about 1-4 infected flocks are detected each year. Layers are tested during the rearing and production periods and before slaughter and in 2013 7 layer flocks were positive.

Cattle are tested at slaughter under the Control Program for NTS in ileocaecal lymph nodes and on carcasses and are tested on farm if there is clinical suspicion of infection. A stamping out and hygiene measure approaches are usually practiced for positive herds with animal restrictions and investigation of the farm and feed supplier, clean up and re-testing. The number of new herds infected varies from 4-13/yr. Pigs are similarly managed with few or no herds positive and a very low number of positive lymph nodes positive.

Carcass neck skin and equipment samples are tested for all NTS serotypes at slaughter and cutting plants and detection of positive lots are followed by corrective actions e.g. traceback, cleaning and disinfection and establishments are required to be NTS negative in a follow-up testing regime. In 2012, one of 5,153 neck skins was positive and none of 903 cutting plants tests were positive. Similar programs apply to pig slaughter and in 2012 about 5,000 samples from pre-chill carcasses and plants were negative. A small number of imported red meat carcasses were positive. Eggs are not included in the National Program although they are tested in-house. Eggs from positive layer flocks can only be sent for egg product manufacture.

Campylobacter spp.

Public health and economic burden

Campylobacteriosis is currently the most common foodborne microbial pathogen in the UK with most cases recorded as sporadic and the ratio of unreported to reported cases about 9.3:1 (O'Brien, 2014). Illnesses result in less hospitalisations compared with salmonellosis reflecting a lower level of acute disease. There has been a steady increase in reports, a slight decrease occurred in 2013 only to be followed by an increase in 2014 with 70,353 notifications of laboratory confirmed cases in the UK (Figure 10) (UKGov, 2015). *Campylobacter* infections, mostly caused by *C. jejuni*, were estimated to cost the UK about £900 million (UKFSA, 2016a).

Food attribution

About 60-80% *Campylobacter* infections have been estimated to be attributed to poultry consumption with other sources including red meat, unpasteurised milk, and untreated water recognised (UKFSA, 2010). Retail chicken was surveyed in 2007-2008 and 65% fresh chicken was positive. In the EU baseline survey of *Campylobacter* in broilers that year, the weighted EU mean prevalences were 71.2% for batch caecal content samples and 77% for broiler carcasses (skin samples) while the estimated UK prevalences were 75.3% and 86.3% respectively. MLST typing has been used to support the attribution of poultry meat as a main food source (EFSA, 2014).

Risk management and regulatory approach

In view of the increased human burden of campylobacteriosis, the UK FSA has undertaken food attribution studies that clearly identified chicken as the major source of foodborne campylobacteriosis and the primary target in risk reduction measures (UKFSA, 2016a). Advanced pathogen reduction measures were initiated to address this. Production of poultry meat comes under the same general UK and EU regulations as described for NTS above. The EU FSA conducted a quantitative risk assessment of *Campylobacter* in broiler meat to inform regulatory approaches (Cited 25/04/16 and available at http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/2105.pdf). The EU baselines included 71% caecal carriage and 75.8% carcass prevalence and the carcass counts varied from 3.8% to 98.6% <10 CFU/g and 0% to 31.9% > 10,000 CFU/g. Carcasses are sampled by testing neck skin. The general approaches concluded from the risk assessment and the performance targets and risk reduction expected in the EU settings were:

- reduction of numbers of *Campylobacter* in the intestines of birds at slaughter by 3 log₁₀ units, would reduce the public health risk by at least 90%;
- reducing the numbers on the carcasses by 1 log₁₀ unit, would reduce the health risk by between 50 and 90%; and,
- and reducing counts by more than 2 log₁₀ units would reduce the public health risk by more than 90%.

The UK FSA has designated responsibility for the *Campylobacter* Risk Management Programme to a Joint Working Group on *Campylobacter*, a partnership between industry, retailers and DEFRA, to drive the initiative and has developed a Joint Action Plan to identify and implement interventions.

Food Safety Strategies and Campylobacter

The pathogen reduction strategy before 2010 was commodity specific with the intent to achieve a 50% reduction of *Campylobacter* positive UK-produced chickens and this Strategy had limited success. The Strategy for 2010-2015 was to develop a pathogen-specific risk management approach bringing together the whole chicken food chain in what has been promoted as the “Acting on *Campylobacter* Together” campaign. Those who pledged to support the campaign included government agencies and policy-makers, farmer’s unions and assurance scheme agencies, poultry industry groups and major companies, major supermarkets and retailers, consumer organisations and the public. There has been considerable investment in surveys and coordinated research studies to accumulate evidence for and to support control measures, and for program evaluations. The 2010-2015 supporting research program had two approaches to support reduction in health risk: reduce the level of the bacterium in the farm-animal hosts and reduce the potential for cross-contamination through the food chain which follows the risk assessment outcomes. These activities have been both completed and are ongoing and can be accessed via the FSA *Campylobacter* webpage at <https://www.food.gov.uk/science/microbiology/campylobacterevidenceprogramme>. It is only possible to describe some key aspects here.

The Strategy had an overall health goal to reduce the levels of human *Campylobacter* illness by half. A specific pathogen target reduction level set to achieve this was based on a decrease in the proportion of the most contaminated raw chickens as high counts were assessed to have a greater effect on health risk (Nauta et al., 2009). The target was to reduce the number of those chickens at post-chill with *Campylobacter* levels of >1,000 cfu/g, from a baseline of 27% in 2008 to 10% by 2015 with an interim level of 19% by 2013. Three band levels of counts were set from high to low, >1,000, 1,000-100 and <100 cfu/g. Those carcasses with low counts were expected to either remain at the same level of contamination or improve (UKFSA, 2010). It was estimated this would result in a reduction of estimated illnesses of up to 30% or about 111,000 cases/yr. The targets were set using the FAO/WHO Risk Management Tool for the Control of *Campylobacter* and NTS in Chicken Meat available at <http://www.fstools.org/poultryRMTTool/> and the CCFH Guideline on control of *Campylobacter* in chicken meat, and using UK data obtained from monitoring, surveys, research and expert opinion. The performance of individual interventions and the cost effectiveness was not definite and a review in 2103 was planned to amend the plan as required.

In 2013, no change was seen in the contamination levels of fresh chicken compared with 2008 levels. Therefore, a “roundtable” of stakeholders was called to discuss the poor progress where it was agreed there was a need for a change, for the issue to be considered both a technical issue, and also as a business issue from the business board level down. Multiple interventions across the chain were identified as needed together with a change in culture to put in place actions that improved microbiological quality. The actions agreed to, progress updates and evaluation results are provided on the Acting on *Campylobacter* Together Campaign information sharing website at <http://www.campylobacter.org.uk/> (accessed 15/04/16). The key intervention points based on science conducted since 2009 and supporting culture/behaviour changes that were required are summarised.

Change of food safety culture through chain. A whole of chain commitment that occurred from the top down in businesses involved was requested. This has resulted in commitment and collaboration

between major supermarkets/retailers and their poultry suppliers who have taken the reduction of contamination levels as a top priority using both traditional and new approaches.

Information sharing. A need for an increase in the amount of information of *Campylobacter* incidence levels along the production chain was identified. Subsequently, this information was shared and made publicly available identifying the reporting businesses as an incentive to improve performance.

On farm interventions. The effectiveness of farm assurance schemes was improved, with improved audits and more stringent codes and standards, particularly in implementation of farm biosecurity.

Farm biosecurity measures included:

- Defined biosecure areas for farm and shed entry and equipment cleaning,
- Foot dips at entry to each biosecure area used by all who enter,
- Disinfection of vehicle wheels and equipment on entry to farms,
- Physical barriers and footwear change at entry to each biosecure area,
- Standard Operating Procedure for catching with reference to biosecurity which included health & safety, hygiene and bird welfare requirements,
- Staff on all types of units (breeders, broilers, free range) required a poultry passport – a qualification for their role in poultry production, which includes a biosecurity module.

The FSA reports a study of 16 farms over 2 yr. to assess whether it was possible to consistently exclude or reduce the levels of *Campylobacter* during production using agreed biosecurity controls. *Campylobacter* counts in caeca and on neck skins were measured on control (6 farms) and model farms (10 farms) with enhanced biosecurity, populated at the same time, and with the same welfare standards (Table 7). It was concluded that the standards used on model farms alone were not able to totally protect chickens from colonisation with *Campylobacter*. Not all sheds become positive with existing biosecurity measures although fewer sheds became positive with the enhanced biosecurity measures.

Table 7 Enhanced biosecurity interventions and the effect on colonisation of *Campylobacter* in chickens when compared with standard biosecurity measures in a UK FSA study (Acting on *Campylobacter* Together Campaign information sharing website at <http://www.campylobacter.org.uk/> accessed 15/04/16)

Intervention on model farms	Results
<ul style="list-style-type: none"> • Each shed a biosecure area with protective clothing and equipment shed specific. • Increased biosecurity during thinning and crating and transport initiatives. • Depopulation – clearing shed within 5 days of thin to reduce <i>Campylobacter</i> load if introduced during thinning. • Shed rest – extending time between flocks while not compromising commercial operations. 	<ul style="list-style-type: none"> • 50% negative at thinning were positive at depopulation in controls, • Stopping thinning would result in 12% reduction in colonisation rate. • Slightly significant association between >5 days between thinning and depopulation and crops being positive. • Strong link between increased time shed left empty and decreased caecal count at thinning.

Offering of financial incentives to farmers producing flocks free of *Campylobacter* has been evaluated (Table 8). Three farms with 25 sheds with good biosecurity were sampled over 3 summer months at thinning and depopulation. The trends on the small sample size of the study gave confidence for a larger study as this could mitigate against summer peaks in prevalence and drive farmer incentives through knowledge of biosecurity controls.

Table 8 Evaluation of farmer financial incentives for producing *Campylobacter* free flocks in the UK (Data from <http://www.campylobacter.org.uk/neck-skin-reduction/> accessed 15/04/16)

Production stage	Percent positive sheds (PCR detection)	
	Control 2012	Farmer incentive 2013
Thinning	58	40
Depopulation	68	71
Combined	64	57

Crate and module hygiene. *Campylobacter* were shown to form biofilms in chicken juice on surfaces and on equipment soiled by birds. Investigations have identified that minimal standards for visually cleaning transport crates and modules may be inadequate to remove biofilms. Recommendations included minimising time crates and modules are left around chicken houses, and, more importantly, creating cleaning/washing systems that remove biofilms. Higher wash water temperature was an option although this would require improved materials tolerating washing conditions for plastic crates. This is being investigated.

Processing and carcass decontamination treatments. Investigations are underway for improved scalding efficiency e.g. use of secondary or multi-stage equipment.

Carcass washing at consistently high efficiency has been shown to reduce *Campylobacter* levels by up to 10%. The use of decontamination measures, treatments and antimicrobial washes on carcasses is restricted by EU regulations and cannot be applied as in the USA and NZ. The FSA encouraged investigation of appropriate options and would consider how regulatory acceptance could be achieved for novel approaches. Some of the investigations are summarised.

- The use of steam and ultrasound (SonoSteam) has been evaluated by a processor who has taken up the technology as a major investment. It was shown to reduce *Campylobacter* on neck and breast skin by 80%.
- Use of electrolysed water and chlorine dioxide (up to a maximum level of 0.5 ppm) in the carcass wash were evaluated and not found to be more effective than potable water washes in reducing levels on neck skins.
- Neck skin is a heavily contaminated part of the birds after processing and trials were conducted on the effect of reducing the neck skin length on *Campylobacter* levels. Shortening the neck skin experimentally resulted in a 0.9 log₁₀ reduction in *Campylobacter* counts (standard 4,740 vs no neck skin 632 mean cfu/ml) in a limited trial of whole carcass rinses. There was not a significant effect in practice and after storage that would impact on the overall risk and there was a decrease in meat quality and appearance following cooking.
- Preliminary studies of various chill treatments are supported such as rapid surface chilling using nitrogen sprays. Initial trials have resulted in a 1-1.5 log₁₀ reduction and further inline assessments are underway.

Retail interventions.

Novel packaging, double bagging or roast-in-the-bag, has been adopted by many retailers. This removes the need for food preparers to directly handle raw chickens as the bagged chicken is placed in the oven, cooked, and the bag cut open before the end of cooking only. These are labelled by a retailer as "Washed and ready to cook".

Retailers have been taking their own initiatives working with their biggest suppliers as part of the co-operative campaign. For example, one upmarket retailer together with a major supplier lists 5 initiatives trialed that has the support of the FSA as they have in combination lowered the

contamination rate from 11% to 5% in a few months (Elliott, 2016). The trials included: farmer bonuses, zero thinning, blast surface chilling, clear labelling, and double bagging.

Process verification and monitoring

The UK government undertakes national microbiological food surveillance linked with their Food Safety Strategies to monitor and review progress (EFSA, 2014). Quarterly surveys of fresh whole chilled chicken and packaging from retail outlets, smaller independent stores and butchers have been undertaken UK -wide since February 2014. The EU required a quantitative monitoring program of broiler slaughter batches (caeca) and carcasses (neck skin) post chill over 3 yr. from 2012-2015 to monitor changes and to provide baseline data for their risk assessments.

In the EU *Campylobacter* is acknowledged to be present in a high percentage of chicken and turkey flocks and carcasses and is not a food safety criterion.

Communication

Communication has been a key activity in control measures. This has included sharing information among all stakeholders, sharing data to inform and as an incentive for improvement, establishing collaborative research groups etc.

UK FSA provides an online resource available at <http://www.campylobacter.org.uk/> for the Acting on *Campylobacter* Together Campaign sharing information on the status of *Campylobacter* in the UK along with research and progress in activities and press releases.

Involving and informing consumers with consistent information on safe handling and cooking raw chicken has been a significant part of the campaign. “The 2015 Chicken Challenge” was available on the FSA website at <http://webarchive.nationalarchives.gov.uk/+http://www.food.gov.uk/news-updates/campaigns/chicken-challenge-2015> and was an interactive site for consumers. The key messages on safe handling of chicken were:

1. Store raw separately, covered, chilled at the bottom shelf of the fridge;
2. Don't wash raw chicken to prevent splashes around the kitchen;
3. Wash all contact surfaces and hands with soap and hot water; and
4. Cook thoroughly, no pink meat, steaming hot and juices run clear.

The UK has not recommended temperatures and the use of thermometers to monitor cooking.

The Strategy for 2015-2020 includes further studies to increase the UK FSA's evidence base (UKFSA, 2016c):

1. Surveys of retail contamination levels and slaughterhouse monitoring,
2. Extended on farm testing of broilers,
3. Independent validation of industry *Campylobacter* interventions,
4. Investigation of human behaviours in a changing environment,
5. Enhanced molecular (MLST/WGS) surveillance and source attribution of infections.

Evidence for success

Campylobacteriosis incidence and outbreaks

There was a peak in notifications of laboratory-confirmed *Campylobacter* infections in the UK in the late 1990s, followed by a downward trend until 2004. Since then, and including from the first FSA Strategy in early 2000, there has been a steady increase in the numbers. A slight decrease occurred in 2013 only to be followed by an increase in 2014 to 70,353 notifications of laboratory confirmed cases (Figure 10) (UKGov, 2015). Using illness as an indicator, the impact of increased pathogen reduction

efforts since 2013 cannot be commented on as annual illness data is available only up to 2014 which is the time contamination of chickens was showing promising downward trends.

Food contamination

Chicken

The FSA Strategy set in 2005-2010 was their first to set a specific target for *Campylobacter* where a commodity based target for a 50% reduction of *Campylobacter* was set for chickens at retail sale. This target was not met by 2009 and cases of illness continued increasing (UKFSA, 2010). This was followed by a new risk based target set for 2010-2015 to reduce the level of highly contaminated birds to 19% by 2013 and 10% by 2015. In a structured official monitoring program in 2013, 298/473 (63%) neck samples and 66/125 (53%) caecal samples were positive for *C. jejuni* (EFSA, 2014). Enumerations of *Campylobacter* in positive samples showed no statistically significant difference in the percentage with counts >1,000 cfu/g between 2008 and 2013.

The prevalence and levels of *Campylobacter* on quarterly monitoring surveys since February 2014 have been promising with a decrease in contamination levels occurring (Cited 17/04/16 at UK FSA at <https://www.food.gov.uk/science/microbiology/campylobacterevidenceprogramme#toc-5>). In 2014-2105, 73% of more than 4,000 chickens tested positive and 19% were in the highest band of contamination; 7% packaging were positive with 0.1% at the highest band. In the second quarter of testing (966 samples), 59% were positive, down from 74% in the same months in 2014 and 11% of chickens tested positive in the highest band, down from 19% in the last quarter of 2014. The results for individual retailers were made available as planned on the FSA site.

In April 2016, the UK FSA suspended the nationwide survey due to inconsistencies in the sampling methods (Reported in World Poultry April 25, 2016 at <http://www.worldpoultry.net/Health/Articles/2016/4/Campylobacter-survey-suspended-in-the-UK-2794590W/>). Sampling was based on collection of neck skins and it appears some processors are removing the neck skin making comparison between retailers invalid. On the other hand, this may reduce the level of contamination on birds as described above.

Consumers

Communication has been a key component of the Strategy and some studies funded by the FSA on consumer behaviours and knowledge to inform communication have been published. *Food and You* is a FSA survey of UK adults over 16yr. used to collect qualitative data annually on the public's behaviours, attitudes and knowledge related to food issues including food safety. Reports can be found at its designated webpage at <http://www.food.gov.uk/science/research-reports/ssresearch/foodandyou>, cited 20/04/16. In the 2014 survey of about 3,500 persons self-reported behaviour on messages relevant to *Campylobacter* consumer campaign messages were included. About half reported using separate cutting boards and 42% reported never washing poultry before cooking, and 36% never washing chicken in particular. The majority (82%) reported cooking food thoroughly as recommended and 91% compared with 88% in the first survey in 2010 reported never eating chicken that was pink or had pink or red juices. Younger respondents (16-24 yr.) were less likely to report practices in line with those recommended.

Consumer's self-reported kitchen behaviour and perceptions related to *Campylobacter* were studied by a group in Manchester (Millman et al., 2014). No evidence of differences was found in kitchen hygiene reported between those that had suffered campylobacteriosis and those who had not. The authors recommended consumer messages need to be more effective with a focus on those groups such as the young many of whom do not appear to perceive themselves as at risk of foodborne illness.

Qualitative ethnographic methods were used by a research group at Hertfordshire to observe practices in homes and understand reasons for behaviour (Dickinson et al., 2014). They found food safety was not considered important or was misunderstood and participants often used common sense rather than heed expert advice.

Iceland

Iceland has had a notable experience with control measures for *Campylobacter* in chicken meat. Iceland experienced an increase in human campylobacteriosis reports from 1998 that was linked with the authorisation and sale of chilled broiler meat, and, increased consumption of this meat, compared with prior years when only frozen domestically produced meat was sold (EFSA, 2013a). A national surveillance programme was introduced voluntarily in 2000 and mandated in 2002 that aimed to prevent the distribution of *Campylobacter* positive carcasses or chilled meat. All positive flocks or slaughter batches had to be frozen or heat treated. As the test results at slaughter take 2 days, this meant occasionally positive carcasses could be distributed. Therefore, during peak seasons, only carcasses from negative flocks (pooled faeces) tested 2-5 days prior to slaughter can be distributed chilled. If no pre-slaughter test is available pooled caeca of 10 birds per batch are collected and a test and hold policy applies.

The driver for the program is market incentives linked with the *Campylobacter* status of the flocks or carcasses. Important voluntary interventions on farm are biosecurity and no thinning of flocks is preferred. Since 2005, farmers have tended to slaughter birds younger (approximately 32 days) during the summer as they have lower prevalence. Since 2008, fly nets have been used on broiler house inlets during summer on high risk farms which are those where all-in, all-out methods cannot be used.

The *Campylobacter* prevalence in flocks and the incidence of human campylobacteriosis has decreased dramatically and chicken is no longer considered the primary source of human infections. The detection rate in broilers in 2013 pre-slaughter was the lowest recorded at 1.4% and the rate in chilled chicken meat between April to October, 2013 was 1.9%. The human rate of infection has not decreased further in recent years and other reservoir sources are being investigated.

Listeria

Public health and economic burden

Most cases of listeriosis in the UK have been sporadic although MLST and WGS have been successfully used to improve investigations by linking cases, and by linking clusters of cases with food sources. The UK experienced an increase in listeriosis cases in 1987-1989 and a sharp increase occurred from 2001 that remained at that level until 2009 (Figure 14). The cases fatality rate has ranged from 17-36% with the highest levels during 2005-2010 (PHE Gastrointestinal Infections Data 2014, cited 17/04/16 at (https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/404560/Listeria_surveillance_summary_2014.pdf)).

Notifications have been associated with specific groups and foods within the community and this knowledge has been important in the development of prevention measures. The second peak involved a high proportion of cases aged over 60yr. often with underlying health conditions. Cases among ethnic minority pregnant women and among people living in deprived areas of England and Wales increased from 2005.

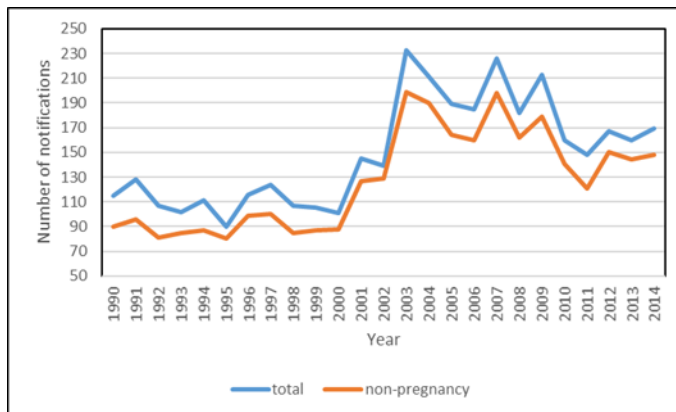


Figure 14 Laboratory-confirmed cases of listeriosis in the UK 1990-2014. Data from PHE Gastrointestinal Infections Data 2014

(https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/404560/Listeria_surveillance_summary_2014.pdf; cited 17/04/16)

Food attribution

The late 1980's peak in listeriosis was attributed partly to consumption of contaminated pate (ACMSF, 2009). In the second extended peak in the 2000s, the most common food source has been RTE food with an extended shelf life and able to support the growth of *L. monocytogenes*. Outbreaks occurred in association with consumption of hospital sandwiches, butter, and sliced meats. The contributing factors for the sporadic infections have been related to consumer handling practices such as failure among older adults to comply with use-by dates on chilled RTE foods.

Little et al (2010) used the Hald *Salmonella* Bayesian source attribution model to quantify the contribution of different foods during 2004-2007 (Little et al., 2010). Multicomponent foods (sandwiches and prepacked mixed salad vegetables; 23.1%), finfish (16.8%), and beef (15.3%) were the most important food sources for the overall population and were similar for the elderly population of ≥ 60 yr. (multicomponent foods [22.0%], finfish [14.7%], and beef [13.6%]). For pregnancy-associated cases, beef (12.3%), milk and milk products (11.8%), and finfish (11.2%) were the most important sources of infection. Linking source attribution with serotyping, the pregnancy cases were more often caused by serotype 4b amplified fragment-length polymorphism V compared with others.

Risk management and regulatory approach

Listeriosis has been identified as a priority foodborne illness due to the incidence and high mortality rate particularly in high risk and vulnerable groups. Unlike the other major pathogens, the food sources to be targeted are diverse although they are commonly RTE chilled foods that support *L. monocytogenes* growth.

The General Food Law in EC Regulations and the UK, Food Safety and Hygiene Regulations mandate the use of HACCP-based food safety programs, general hygiene, appropriate training of food handlers in the manufacture of these foods and set microbiological criteria for *L. monocytogenes* during the shelf life of products. The measures used by industry focus on preventing contamination during food processing and preventing growth in potentially hazardous foods through product formulation and shelf life restriction (UKFSA, 2009b). Use-by date labelling for safety is a legal requirement. Guidance is available on studies that can be used to determine the potential for growth of *L. monocytogenes* in a product and how to demonstrate compliance. Trade organisations are supportive (e.g. British Retail Consortium and Chilled Food Association) and require members to comply with specified hygiene standards and audit against these.

The food industry generally has implemented controls for the last few decades and the incidence and levels of the bacterium in the riskier foods from large manufacturers at the point of production or sale has not increased since the 1980s (ACMSF, 2009). These businesses undergo frequent certification audits with third party food standards. Small to medium enterprises on the other hand have become a concern as they may not have the same understanding of and compliance with the Regulations and with application of microbiological criteria for *L. monocytogenes*.

Food safety criteria

EC Regulation 2073/2005 (<http://faolex.fao.org/docs/pdf/eur61603.pdf>) states food businesses manufacturing RTE foods shall test product and also food processing equipment and environments for *L. monocytogenes*. Food safety criteria for this pathogen are established for RTE foods and are based on both presence/absence and maximum enumerated levels acceptable depending on the ability of the foods to support growth (Annex 7). More stringent criteria are applied to RTE foods for infants and those for special medical purposes.

Listeria Risk Management Programme

The FSA Strategy 2000-2005 was commodity specific and did not address *Listeria* specifically. It was during this period that the number of illness reports increased dramatically and the UK FSA established a *Listeria* Risk Management Programme as a priority action for *L. monocytogenes* to support achievement of the FSA Strategy 2010-2015 i.e. the number of cases of listeriosis would be lower than in 2010 (UKFSA, 2009b). The approach was to be pathogen specific and targeted within a coordinated and actively managed strategy. The Programme was developed on available evidence and included the 3 primary work streams described below.

Consumer behaviours/actions within the community

Consumer focused activities were undertaken to promote awareness of the risks of listeriosis and of behaviours and actions that could prevent the illness among key vulnerable groups via those responsible for caring and advising these groups within the community.

Vulnerable groups identified were: persons over 60yr., persons with medical conditions living independently, those on immuno-suppressive drug therapy, economically deprived groups, and pregnant women in minority ethnic groups. Grouping vulnerable persons according to how they interacted with the health care system was sought and messages tailored to the groups identified. Research into refrigerator usage and temperature control was undertaken to inform messages. Messages could be delivered direct and through health care professional and non-government organisations.

Procurement/provision of food to the vulnerable in care

Activities were proposed to ensure that listeriosis was considered as a risk in the food procurement and food safety management programs in settings where vulnerable persons were cared for in the UK. This was achieved with the development of the "Guidance for healthcare and social care organisations available in draft form at <http://www.food.gov.uk/sites/default/files/proposed-listeriosis-guidance.pdf>.

The target group for this activity was initially the National Health Service hospitals working within the existing regulatory framework for food supplied in this sector. It was recognised that often the persons in healthcare settings responsible for food service may not be the catering staff so that the guidelines had to be appropriate for all personnel potentially involved. It also considered managing food brought into facilities for patients by family and friends. Key targets were applying the appropriate level of stringency of microbiological criteria for vulnerable groups and appropriate food

safety management systems with strict controls to prevent and minimise the risk *L. monocytogenes* in food. The guidance specifies that there should be no need to limit or restrict the menu choice of foods offered to vulnerable patients/residents.

It is important that nutritional needs of the patient/resident are balanced with that of the risk of listeriosis. With appropriate food safety controls in place there should be no need to limit or restrict menu choice for vulnerable individuals.

Industry compliance/enforcement

Action was taken to improve compliance of high-risk food industry sectors that have existing legal requirements for *L. monocytogenes* in foods and to ensure robust and consistent enforcement.

High risk foods were identified from surveys (cooked sliced meats, meat/fish/vegetable pates, smoked fish, pre-packed mixed salads, pre-cut fruit, sprouted seeds, pre-cut salad vegetables and sandwiches), outbreak investigations (RTE meat/meat products, cheese, fish/shellfish or sandwiches/sandwich fillings), and food attribution studies. In studies of economically deprived neighbourhoods, people were more likely to purchase food from convenience stores and local food outlets. These outlets were at the smaller end of the market and were frequently linked with lower microbiological food quality. Therefore, the primary target businesses were small to medium enterprises producing higher risk foods e.g. cooked sliced meats, smoked fish, soft mould-ripened and soft blue cheeses, and sandwiches.

In particular, understanding by small businesses and enforcement officers of the application of food safety criteria that defines the limits of *L. monocytogenes* in RTE foods was identified as lacking. The relative risks of different food types at different points in the food chain for different vulnerable groups was investigated and modelled to assess the impact of intermediaries on listeriosis risk e.g. butchers, delicatessens. The outputs were guidance documents that would improve on prior guidance material in the level of understanding of technical content, decision support tools for risk management, and training materials developed together with large enterprises and industry groups.

Evidence for success

Listeriosis incidence and outbreaks

The pattern of laboratory-confirmed reports of listeriosis in the UK had begun to fall at the beginning of the *Listeria* Management Programme in 2010 (Figure 14). However, the numbers did not fall below pre-2001 levels, were higher than in 2010, and have increased since 2011 with a 5.2% increase between 2013 and 2014. Understanding changing case and food risk factors and modifying response has played a role in controlling listeriosis from year to year. In 2014, a high proportion of listeriosis among females was reported, as were cases in ethnic minority groups and cases of bacteraemia in people ≥ 60 yr. (PHE Gastrointestinal Infections Data 2014, cited 20/04/16 at https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/404560/Listeria_surveillance_summary_2014.pdf). Pregnancy associated cases increased from 10-12.4% and some of these were in the ethnic minority groups. There was a higher proportion of non-pregnancy female cases aged 0-9, 30-39 and 70-79 yr. and it is not known if this a new trend in gender and age of cases.

Three outbreaks were reported in the UK in 2014; 2 were linked with crustaceans and shellfish and one with other foods unidentified (UKGov, 2015).

Food contamination

RTE cooked and cured sliced meats and fermented and cured meat products at retail sale in small and medium-sized enterprises were surveyed for *L. monocytogenes* (detection and enumeration), physical and chemical parameters, storage temperatures and use-by-dates as a measure of compliance with

regulations and guidelines in 2012-2013 (UKFSA, 2013a). Of 1,049 samples, *L. monocytogenes* was detected in 3.8% (7% *Listeria* spp.), samples from 27% of producers with 23 producers having a prevalence of 25% positives. The prevalence was twice that in a prior EU survey where foods were tested at the end of shelf life and in previous UK surveys that had focused on major retailers. The mean storage temperature was 6.8°C with 71.3% above the guideline of 5°C, and 32.7% above 8°C (UKFSA, 2013a). The FSA had shown in 2006-2007 that storage at a temperature above the guidelines at 6±2°C increased detection by 0.5%. The other parameters were mainly in a range where growth of *Listeria* spp. could take place.

Overall the study provided evidence for the needs within this small and medium-size enterprise sector, in particular, to inform and train staff about maintenance and control of refrigerated display cabinets and for investigations of manufacturers with appropriate corrective actions being taken.

Consumer behaviours/actions within the community

Informed consumers using safe practices is a key component of the Strategy and there has been some assessments and research to support development of risk reduction measures. In the FSA *Food for You* survey, just over half the respondent with a fridge self-reported they knew the correct fridge temperature (0-5°C); 11% checked the temperature at least monthly with a thermometer and half never checked the temperature.

A survey of older adults and their self-reported behaviours of time and temperature control of RTE products was undertaken in Wales (Evans and Redmond, 2016). They observed that this age group reported they knew about use by dates; however, they had neutral attitudes and would eat the food beyond their shelf life. It was concluded older adult's food safety cognition may also affect their behaviours and this is a challenge to be considered.

A qualitative ethnographic approach including kitchen tours, photography, videos, diaries and interviews, was used to understand domestic kitchen behaviour among older adults (Dickinson et al., 2014). A complexity of underlying influences that need to be considered for this group was identified. Factors with the potential to influence safe behaviours were level of trust in the food supply, use of use by dates and preferred links with sensory logic, and concern for food waste. Practices changed with their circumstances e.g. increased frailty, bereavement, living alone, receiving help with care and ability to acquire new knowledge.

In the 2015-2020 FSA Strategy further research of consumer tolerance and perception of different food risks will be undertaken.

Procurement/provision of food to the vulnerable

The *Listeria* guidance for vulnerable persons in care has been drafted and in the FSA Strategy 2015-2020, an evaluation of the impact of the guidance document will be undertaken using indicators from a representative national sample of healthcare/social care organisations and a longitudinal comparison of changes in risk-related practices (UKFSA, 2016c).

New Zealand

Evidence of health and economic burdens of foodborne illness

Annual reports of foodborne diseases in New Zealand (NZ) are published by the Ministry for Primary Industries (MPI) in collaboration with Institute of Environmental Science and Research Limited (ESR) and provide data and an interpretation of illness, food attribution and progress of pathogen reduction strategies (NZMPI, 2015a). NZ chose 3 pathogens for performance targets for foodborne illnesses

notified: campylobacteriosis as it was the most common, listeriosis as it was the most severe, and salmonellosis for comparability with the UK and USA monitoring programmes (NZMPI, 2015a).

Estimates of the mean cases/yr. of foodborne disease in NZ were updated in 2011 and included; campylobacteriosis – 63,800 (90% CrI, 43,000-90,000), salmonellosis – 6,300 (90% CrI, 1,600-15,500), and listeriosis (non-perinatal) – sepsis 7.0 (90% CrI, 3-12), meningitis 9.9 (90% CrI, 5-15), and deaths 2.6 (90% CrI, 0-6). The total foodborne DALYs estimated for these diseases were 540, 67 and 160 respectively (Cressey, 2012). Food attributable proportions have been estimated using results of a risk ranking project based on expert consultation. Most listeriosis cases are considered foodborne excepting perinatal cases while the other pathogens were estimated at about 62-64% food related (Table 9). The cost of foodborne illness was estimated in 2007 to be \$NZ99 million using dollar values at the time (Duncan, 2014). The annual data for 2014 were the latest cited at the time of writing (Table 9).

Table 9 Surveillance data for notified cases of campylobacteriosis, salmonellosis and listeriosis in New Zealand 2014. Data sourced from (NZMPI, 2015a)

Foodborne illness	Number of cases	Notification rate (/100,000 population)	Number of hospitalisations (%)	Number of deaths (%)	Estimated food related cases (%)*
Campylobacteriosis	6,776	150.3	717 (10.6)	0 (0)	63.8 (95% CrI, 44.1-83.2)
Salmonellosis	954	21.2	113 (11.8)	0 (0)	62.1 (95% CrI, 35.2-86.4)
Listeriosis	25	0.6	27(108)	5 (20)	87.8 (95% CrI, 57.9-98.5)

*Based on expert elicitation studies cited in the Annual Report (NZMPI, 2015a)

Food attribution

From expert consultations it was estimated 75.4% of foodborne campylobacteriosis incidence was due to poultry consumption, about 19% salmonellosis incidence was due to poultry consumption and approximately 55% of listeriosis incidence was due to consumption of RTE meats (NZMPI, 2015a).

Federal agencies and food safety

The NZ MPI is responsible for legislation covering all aspects of food safety and extends from farm to fork including production, processing, transport and retailing, it includes all human, pet and animal foods and covers domestic and export food (NZMPI, 2016a). The MPI develops, regulates and implements food standards with FSANZ having a role in developing food standards. The MPI will deliver on the NZ Government strategic goals within their *Our Strategy 2030* and the NZ Government ministry includes a Minister for Food Safety who has reduction of foodborne illness as one of her 5 priority areas. There are several levels of management and groups concerned with delivering pathogen reduction in food. The MPI has a Pathogen Management Group that advises on priority pathogens for MPI's focus, emerging pathogens, and recommendations for change, and this Group has a sub-group that is responsible for achieving the goals of their risk management strategies for specific pathogens (NZMPI, 2013b).

NZ MPI's approach to food safety and pathogen reduction aligns with the CAC approach to risk management under what they formally refer to as their Risk Management Framework (RMF). The RMF is supported by a Food Safety Science Group that provides scientific and technical advice. The RMF uses human health surveillance and other epidemiological studies as indicators of foodborne illness

transmission and in conducting risk profiles and assessments and uses surveillance data for monitoring and review of their risk management performance. Performance targets are established by the NZ MPI annually.

The NZ Food Safety System is made up of the following elements (NZMPI, 2016c):

1. *Regulatory requirements.* Businesses are responsible for developing risk management programs to manage risks and hazards associated with the production, processing, transport and storage of food and animal products. They have additional food standards and joint food standards with Australia for labelling and composition of food;
2. *Compliance and enforcement.* Agencies verify that the regulatory requirements are met on farm, transport and at processing, packaging, labelling, storage and loading for export and undertake compliance and enforcement activity if verification fails, including recalls. Public health units deliver food safety contracts e.g. approvals, inspections and investigations;
3. *Systems assurance.* Monitoring (farm, primary and secondary processing) and testing is undertaken to ensure food production systems are working;
4. *Certification.* This is provided when requirements are met and verified e.g. for exports and market assurance.

Food law and regulation

One of the main food legislations in New Zealand is the Food Act 2014, updated from the Act of 1981, under which all NZ food businesses must operate after March 2016. The MPI described the changes of approach in the new Act as: a focus on food production rather than food premises, a risk based approach to stringency of food safety requirements for businesses.

Food businesses are categorised according to the risk level posed by their business, with food activities that are low risk, either because of the low likelihood of occurrence or low numbers of persons exposed, exempt from food control plans or a national programme. Examples are fund raising and community groups and some businesses although while they are exempt they are still required to ensure food is safe and suitable to eat. Most food prepared and served on marae are not covered by the Act. The NZ MPI provides a tool for food businesses, *Where do I fit?*, so they can find out what rules they need to follow under the Food Act 2014 according to the risk presented by the foods they manage (Cited 24/03/16 at <https://www.mpi.govt.nz/food-safety/food-act-2014/where-do-i-fit/>).

The Food Act 2014 requires a written Food Control Plan (FCP) that outlines the steps the business making or selling higher-risk foods needs to take to make food safe e.g. identification of food safety risks and how they will be managed (NZMPI, 2016b). The FCP has to be registered each year and regularly verified. The NZ MPI mandates under the Food Act 2014 the application of HACCP principles as part of operating a risk-based program together with Good Operating Practices (e.g. GMPs, GAPs etc.) referred to as GOPs. Supporting forms, templates, manuals and guidelines, and a hazard database are provided online.

Alternatively, a food business may operate under a National Programme that requires:

- Record keeping to show they are selling safe food,
- Registration of business detail with a local council, and
- One or more visits from a verifier approved by the NZ MPI.

There are 3 levels of National programme:

- Level 1, low risk – transporters and distributors; horticulture producers and packing operations (pack-houses), retailers of manufactured ice cream and iced confectionary;
- Level 2, medium risk - bread bakeries, manufacturers of jams, chips and confectionery, sauces and spreads;
- Level 3, higher risk - brewers and distillers, food additive, fruit drink and flour manufacturers.

A Risk Management Program is a requirement for processors or manufacturers of animal products and is a written programme for managing hazards, the wholesomeness and labelling of animal material or products that has to be registered with the MPI (NZMPI, 2016b). All primary processors of animal material and products for human or animal consumption (includes certain dairy and secondary processors) are required to operate under a RMP. Exempt are primary producers (beef, sheep farmers), egg producers (≤ 100 birds with direct sales).

A review of the food safety capability of the NZ dairy industry was conducted in 2014 (Available at <http://www.comcom.govt.nz/regulated-industries/dairy-industry/report-on-the-state-of-competition-in-the-new-zealand-dairy-industry/>, cited 31/05/16). The main findings which were recommended for dairy and the wider food safety capability were a need to establish a robust food safety culture from governance level down, including industry organisations and leaders, and for all sectors of the supply chain. Longer term initiatives included enhanced food safety education and training, leadership, a holistic understanding of food safety across the value chains and evaluation of the impact of actions.

Monitoring, verification and compliance

The NZ MPI audits, enforces and monitors the Food Safety System requirements. Food monitoring programs relevant to microbial hazards include mandatory monitoring of meat and poultry for domestic and export markets recorded in the National Microbiological Database (NMD) and an Imported Food Monitoring Programme for imported foods (NZMPI, 2016b).

Verification and compliance is carried out at the territory or other level recognised to be competent and independent and the auditors are referred to as “verifiers”. The MPI manages verification of controls at premises processing meat, seafood and other animal products (NZMPI, 2016a).

The NZ MPI has developed risk management strategies for three foodborne pathogens, *Campylobacter* spp., NTS and *Listeria* as described below.

Non-typhoidal Salmonella

Public health and economic burden

In 2014, the total salmonellosis notification rate was 21.2 cases/100,000 population with an estimated 13.8 not travelled overseas and 8.6 of these transmitted by food (Table 9). The estimated cost of salmonellosis in NZ in 2010 was \$NZ15.4 million, 12% all disease costs (NZMPI, 2010). The pattern of notifications peaks in summer historically although in 2014 peak rates were seen in different months, with 2 troughs in April and November (NZMPI, 2015a). Cases are highest in the 1-4 yr. age group and hospitalisations highest in > 60 yr. age group. The number of outbreaks/yr. between 2005-2014 ranged from 4-18 with quite varying numbers of associated cases.

Serotypes and genotypes

Salmonella serotypes of international concern e.g. Enteritidis PT 4 and Typhimurium DT 104, are not endemic in NZ livestock. In 2014, the serotypes of NTS isolates from 958 salmonellosis cases were Typhimurium 40.9%, Enteritidis 12.1%, Infantis 5.8%, and others (NZMPI, 2015a). Typhimurium phage types vary between years.

Typhimurium was the most common serotype among isolates from non-human sources typed in 2014 with both common and different phage types when compared with human isolates. Brandenburg was the next most common serotype from bovine and ovine sources and this serotype is an important cause of abortion and deaths in ewes. Typhimurium isolates of different phage types were isolated from 3 of 7 outbreaks in 2014 and these types were different to non-human isolates.

Food Attribution

Risk factors for salmonellosis notifications, 2014, were consumption of food from retail premises (50.8%) and overseas travel during the incubation period 34.7%) (NZMPI, 2015a). The first risk factor has been stable since 2010 while the second has been increasing as has recreational water contact. There has been limited surveillance data available to allow attribution of specific foods. In 2014, a suspected vehicle was found in 1 of 7 foodborne outbreaks, a meal of fried rice, beef stir fry and battered fish. Between 2006-2013 there were 3 salmonellosis outbreaks among 21 clusters of illness linked with raw milk consumption, one of which had strong evidence (NZMPI, 2013a).

Risk management and regulatory approach

The NZ MPI has established a *Salmonella* Risk Management Strategy; however, as there was no primary exposure pathway identified the scope of the Strategy initially is broad (NZMPI, 2013e). The baseline incidence used as a target to measure success was set at 70% of the estimated average foodborne transmission rates for 2004-2007. In 2014 the MPI decided to continue with the 2 goals of the 2013-2014 Strategy update: to maintain the 30% reduction in reported annual incidence of foodborne salmonellosis achieved in 2013-2014 (e.g. below 9.9 cases/100,000 population), and to support market access. Note the strategy reporting is based on food attributable cases and not total reported cases of salmonellosis as in the other countries reviewed.

The work programme of the Strategy reported 2010-2014 (NZMPI, 2013e) included:

- Advancing understanding of NTS source attribution and pathways using modelling and NTS genotyping, surveys, literature reviews and improved infrastructure for data management to support strategy and market access,
- Quantification of the impact on risk of control measures along food chains to inform choice of options for risk reduction and PSs criteria review,
- Alignment of Codex principles and ANZ Food Standards Code 1.6.1.

Meat and poultry

Processors of large animals and birds (since 1999) and of poultry (since 2004) have been required to have Risk Management Programmes in which NTS would be a health hazard to be controlled. In addition, PSs are mandated under the NMD (NZMPI, 2013e). NZ requires its NMD testing program to be accepted as equivalent to those in the EU and USA or accepted by other markets for market access of its primary products and this is a strong driver for NTS control.

Rendered animal products are required to be produced under a Risk Management Programme with 2 key requirements: use of a thermal process to inactivate microbiological hazards harmful if consumed by animals and prevention of post-treatment recontamination or deterioration (NZMPI, 2013e).

Monitoring and process verification

The NMD requires mandatory testing for NTS on carcasses post-slaughter and dressing, and primals for some meat species, and poultry carcasses (NZMPI, 2015b). NTS testing of sheep and pigs has not been required as they were considered to have little significance in foodborne salmonellosis in NZ. Approximately 45% of pork consumed in NZ is imported and little evidence is available of the NTS status. The NMD sampling plans and PSs are summarised in Annex 9.

Enumerations of indicator bacteria e.g. aerobic plate count (APC) and *E. coli*, are required for raw meats with tolerance levels set for meat species that are linked with different levels of alerts and actions. If a meat processor detects NTS in a sample, the following are required: report the result, isolates serotyped, stock traced back to their catchment area, and checks for other animal infections or reports. Processors must investigate their operations identifying contributing factors and if a third detection occurs a review of HACCP plans and a NTS management plan are required by the MPI.

The chicken PS for NTS has been based on the USA PS: NTS may be detected in no more than 5 of 51 samples in a moving window. However, as described under the USA review section they are changing their focus to chicken parts. If the PS is breached operators are expected to review their process and livestock NTS status, document contributing factors, and make modification as required to their HACCP plans and pre-requisites and report to the MPI.

Dairy

The sale of raw milk other than farm gate sales of a maximum of 5L was prohibited in NZ under the Food Act prior to this year. MPI conducted a quantitative risk assessment with modelling of the risk following consumption of raw milk purchased from on- and off-farm sites and control measures (NZMPI, 2013a). The mean predicted numbers of illnesses/100,000 servings for 3 scenarios are shown in Table 10. The authors commented epidemiological evidence indicated these estimates are less than those in Australia and may also be an over-estimate of the NZ situation.

Table 10 The mean predicted number of illness/100,000 servings from consumption of untreated raw milk purchased at various sites in New Zealand based on a risk assessment (NZMPI, 2013a)

Place of purchase of untreated raw milk	Mean predicted illnesses/100,000 average servings			
	Campylobacteriosis	Salmonellosis	STEC infection	Listeriosis
Farm gate	139	8	70	<1
Off-farm	124	8	75	<1
Retail	30	7	56	<1

From March 2016, the MPI has deemed raw milk can be sold directly from registered farmers to consumers at the farm or via home deliveries under new requirements of the Raw Milk for Sale to Consumers Regulations 2015 (NZMPI, 2016d). The new regulations impose a Regulated Control Scheme under the Animal Products Act 1999 and impose restrictions under the Food Act 2014. The Regulated Control Scheme's purpose is to *"identify, monitor, evaluate, and manage the risks associated with the production and processing of raw milk and other related activities or conditions affecting the fitness of raw milk under the scheme"*, and specifications and requirements are set out for registered operators. The Food Act regulates risk management programmes, and raw milk sale, labelling and advertising. The requirements are provided in more detail in Annex 10.

Conformance testing at the point of availability to the consumer is specified and includes NTS, *Campylobacter* and *L. monocytogenes* testing once per 10 days as well as indicator tests and uses a demerit scoring system. The pathogens are not to be detected in 5 x 25ml samples. A positive detection is a "critical" non-conformance result and the operator must immediately cease production, processing and supply, and issue an advisory to customers. The advisory includes lot identification, reason, and advice to heat the milk to boiling or discard it. Recommencement of supply requires acceptable results from 5 consecutive lots over at least 5 consecutive days. A "major" non-conformance results from exceeded indicator levels requires the same action except the operators can resume production after 3 conforming consecutive lots over 3 days. Accumulating demerit points can result in suspension.

Other foods

Various foods other than meat and poultry are subject to general regulations and requirements that would include control of NTS as a hazard. Reports for various foods investigated can be found at <http://www.foodsafety.govt.nz/science-risk/programmes/hazard-risk-management/salmonella.htm> (Cited 29/03/16) and some are summarised below.

Eggs. The egg production and packing industries have been required to have a Risk Management Programme since 2003-2004 that includes NTS control although very small producers of <100 birds and direct sales are exempt (NZMPI, 2013e). Secondary processors must have a registered FCP and all finished products come under the FSANZ Food Code. Similar to Australia, NZ does not have SE endemic in flocks and in retail surveys conducted 1994-2007 internalisation of NTS was not found. In 2007, 1.8% of shell surface samples of 514 retail eggs were positive for NTS, all serotype Infantis. An updated risk assessment in 2011 provided an estimate that eggs may cause 10% NTS infections and may cost approximately \$NZ1.5 million based on burden of disease figures. Since 2010, there has been little evidence of a health issue with consumption of eggs (NZMPI, 2013e).

Produce. Produce surveys have been conducted on various fruits and vegetables. Based on faecal coliforms and /or *E. coli* levels 95-97% of 891 imported and domestic conventional and domestic organic fresh fruits and vegetables were of “satisfactory” standard. Approximately half of those rated “marginal” and “unsatisfactory” were leafy greens followed by strawberries, sprouted seeds and capsicums. *S. Typhimurium* was detected in 2 domestic organic lettuces from one grower. Investigations are being conducted on the impact of farm inputs (water, natural fertilisers) on produce safety (NZMPI, 2013e).

Flour. Flour was implicated in a large outbreak in NZ; however, in a risk assessment of cereal grains the risk was found to be low although if contamination occurs it could involve a large number of people. The effectiveness of industry controls was not known. Risk communication of the risks for consumers in consuming uncooked flour products was identified as warranted.

Evidence of success

Salmonellosis incidence and outbreak

The total salmonellosis notification rates fell from a high in 2001, then progressively decreased from 2007-2013 at a rate the MPI described as “modest” (Figure 15). The 30% reduction target in estimated NZ foodborne cases over 5 yr. was met in 2010-2013. The 2014 rate was the lowest since the notification system was implemented.

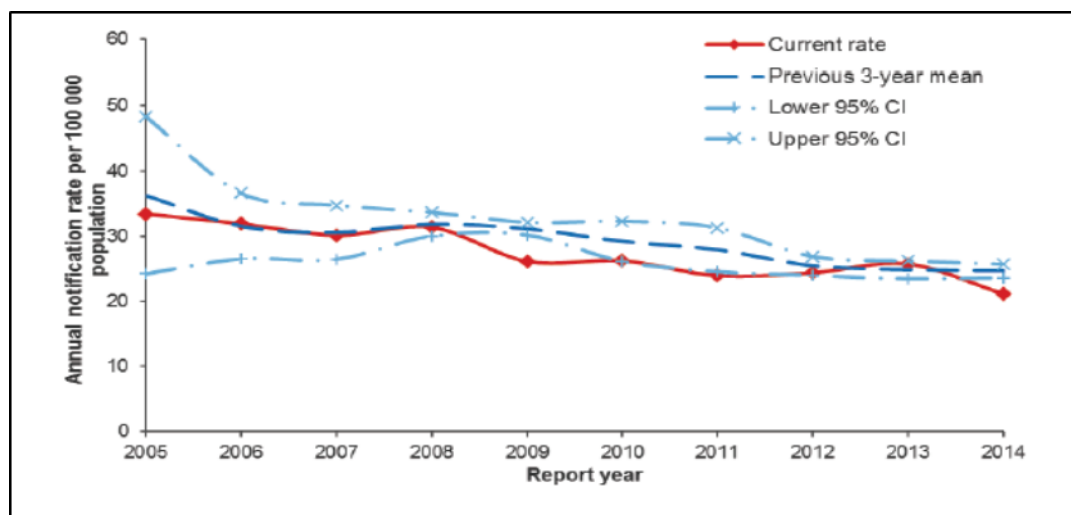


Figure 15 Total salmonellosis notification rates in New Zealand 2005-2014. Reproduction permitted with acknowledgement (NZMPI, 2015a)

Food contamination

The lack of reliable attribution data for NTS illnesses has hampered risk managers in defining targeted actions and this is an area of ongoing investigation applying approaches that been successful for campylobacteriosis. Extensive information has been gathered from attribution studies and microbiological subtyping, scientific evaluations, risk profiles (pork and pork products, cereal grains, high lipid foods made from sesame seeds, peanuts and coco beans, and animal feeds) and surveys (poultry, meat, fresh salads, nuts and seeds) and further investigations are continuing including investigation of sprouts, RTE fruits, horticulture inputs (water and natural fertilisers), NTS behaviour on shell eggs and refrigeration.

The total prevalence of NTS in all animal products regulated by the MPI in the NMD has been trending downwards up to at least 2013. The MPI reports there has been a significant reduction of NTS in raw poultry meat since the introduction of mandatory control measures and this coincides with the downward trend in illness notifications (NZMPI, 2013e). The NTS detection rate in poultry was 0.4% nationally in 2013 (NZMPI, 2013e). When detections of NTS in poultry occur they may be associated anecdotally with contaminated feed.

New regulations for the sales of untreated raw milk have been introduced in 2016 and remain to be assessed in terms of impact on human illness.

Campylobacter

Public health and economic burden

Campylobacteriosis incidence has been significantly higher than any other foodborne illness in NZ (Table 9) and it has been the costliest with estimates in 2010 of \$NZ36 million representing 27% all disease costs (NZMPI, 2010). In 2014, the total campylobacteriosis notification rate was 150.3 cases/100,000 population with 139.9 cases/100,000 population domestic and 89.0 cases/100,000 population of those estimated to be foodborne (NZMPI, 2015a). Campylobacteriosis incidence is reported to increase in summer and varies among NZ regions. The highest illness rates were among children 1-4 yr. and the highest hospitalisation rates were for ≥ 70 yr. olds. There were 117 hospital recorded cases of Guillain-Barré syndrome (GBS) that may be preceded by *Campylobacter* infections and other illnesses.

Campylobacteriosis cases have been predominantly reported as sporadic and not linked. In 2014 campylobacteriosis outbreaks accounted for 4.1% (35/820) of all enteric outbreaks and 1.6% (241/14,235) of all associated cases with 18 (51.4%) outbreaks foodborne.

Food attribution

In 2005, the MPI took an alternative approach to determine source attribution using a representative sentinel site for the study rather than country-wide to strengthen doubt and uncertainty in prior evidence gathered on dominant animal reservoirs and pathways of *Campylobacter* infections using epidemiological studies, outbreak data, risk assessment and expert elicitation (NZMPI, 2014). Source attribution modelling based on molecular subtyping (MLST) was used to identify the primary animal reservoirs or amplifying hosts and their contribution to the burden of campylobacteriosis, and subsequently, to assess the impact of interventions. Strong evidence was found of poultry as the dominant food source at that time. Extensive discussion of the advantages and disadvantages of this approach are provided by the MPI (NZMPI, 2014). While considered a successful approach, practical disadvantages identified were cost of microbiological analyses (humans, foods, animals, environment) and genotyping (if not routine), and the poor discrimination between *Campylobacter* populations in different animal reservoirs using MLST. The latter may be improved using WGS tools in future. A further recommendation from the study was that integration of source attribution modelling, genotyping and evolutionary modelling, together with current epidemiological surveillance/investigations would provide more efficient use of data and valuable information on the efficiency of controls and strategy for regulators.

The most common exposure risk factors for campylobacteriosis notifications, 2014, were consuming food from retail premises (47.4%) and contact with farm animals (39.6%) while consuming untreated water (24.2%) and contacting recreational water (16.2%) were also important. The evidence for a food source in 18 outbreaks in 2014 was weak except for an outbreak due to chicken liver pate. Suspected food vehicles included: raw milk (5), chicken livers/pate/parfait (6), raw chicken (1), lambs fry (1) and unknown (5) (NZMPI, 2015a). Between 2006-2013, 13/21 outbreaks linked with raw milk were caused by *Campylobacter* of which 2 had evidence of a strong association (NZMPI, 2013a). In a sentinel site study, genotyping has proven useful to link otherwise sporadic cases as a strong positive association between illnesses and a cattle-associated strain was found and links made with consumption of raw milk (NZMPI, 2013a).

Risk management and regulatory approaches

Control of *Campylobacter* and poultry have been the priority target since before 2006.

Campylobacter Risk Management Strategy

A considerable amount of risk management analyses and research have been undertaken over more than 15 yr. to inform development of a *Campylobacter* Risk Management Strategy that commenced in 2006 and can be accessed at <http://www.foodsafety.govt.nz/science-risk/programmes/hazard-risk-management/campylobacter.htm> (Cited 15/03/16). The Strategy target initially was a 50% reduction from a baseline average of 2004-2007 in NZ acquired foodborne campylobacteriosis over 5 yr., then a further target was set for a 50% reduction from the 2008-2012 average incidence rate. A cost-effectiveness ranking was undertaken for potential interventions and these are shown in Table 11 (Lake et al., 2013).

Table 11 Cost effectiveness ranking of interventions to control *Campylobacter* in poultry in New Zealand. Data from (Lake et al., 2013)

Intervention and point in chain	Health benefits (DALYs) (%)	Cost /DALY (NZ\$ 2009)
On farm:		
Increased biosecurity on farm for catching gangs	165 (16)	27,000
Single use of catching crates/modules for thinning	82 (8)	9,100
Broiler farms all in, all out	331 (33)	27,000
Bacteriophage treatment chickens pre-slaughter	993 (98)	3,000
Processing:		
Chemical (chlorine) controls	854 (84)	1,700
Freezing what is currently fresh product (75%)	947 (94)	8,900
Irradiation fresh chicken meat	1,010 (100)	43,400
Multiple processing interventions	854 (84)	1,200
Consumer:		
Hygiene education	8 (0.8)	17,900

The capital investment and operating costs to industry over 2007-2008 were estimated at \$NZ 2.014 million and \$NZ 0.88 million, respectively (Duncan, 2014). A cost-benefit analysis of food safety regulation of poultry production was used to demonstrate a positive benefit to cost ratio from reductions in incidence of campylobacteriosis, with gains of \$57.4 million annually (Duncan, 2014).

The MPI Strategy has been broadly based on the following objectives:

- development of targeted controls that are hazard- and risk-based, along identified transmission pathways (e.g. poultry),
- monitoring with targets regularly reviewed and adapted as required,
- promotion of safe food handling among consumers, and
- collaboration between agencies, researchers, industry, and the community within NZ and internationally on risk management (NZMPI, 2013b).

Intervention measures undertaken by the NZ poultry industry (NZMPI, 2013d) have included:

- development of a voluntary broiler growing biosecurity manual building on existing manuals and Code of Practice for primary producers,
- improved catching and transporting of birds e.g. single use and proper cleaning and drying between uses of catching crates daily,
- adjustment of primary processing conditions e.g. immersion chiller temperature and pH, chlorine use and water flow; and,
- voluntary use of leak proof packaging of retail poultry.

Technical interventions that have been identified as important by the poultry industry included:

- maintenance, adjustment and, if required, replacement of vent opening and evisceration equipment; and
- implementation of sprays to ensure that carcasses are washed after processing steps with the potential for contamination.

The Strategy taken has been to allow businesses to choose the risk management options for their establishment provided they can demonstrate they achieve the mandated level of performance at the end of processing (Lee et al., 2015).

Monitoring and process verification for poultry

The NMD specifies a process monitoring program and verifiers visit establishments twice per processing season (NZMPI, 2015b). In 2007 the NMD specified a testing programme of the caeca of incoming birds at poultry processing plants based on a pooled sample from 10 birds per cut per shed; however, this was discontinued in 2009. The quantitative testing of carcass rinse samples for *Campylobacter* at the end of primary processing was included in the NMD and poultry processing performance targets were set in 2008 to meet the health objectives. The sampling requirement for whole carcasses and *Campylobacter* testing and the PSs in the NMD are provided in Annex 9. The PS for *Campylobacter* in poultry is referred to as the *Campylobacter* Performance Target. Levels above $3.78 \log_{10}$ cfu/carcass in 7 or more of 45 individual carcass samples in a moving window and having more than 29 of 45 samples above $2.3 \log_{10}$ cfu/carcass (limit of detection) in a moving window is a non-compliant result (NZMPI, 2015b). A processing period is 5 days so that 15 samples are collected with 3 samples/day using a moving window over 3 processing periods or 3 samples/week and 9 samples over 3 weeks for low throughput establishments. Regulatory moving window limits were set in 2013 and are provided in Annex 9.

Responses required for non-compliance escalate with each non-compliant moving window and include reporting to MPI and initiation of corrective actions to restore control. For 6 non-compliant events the operator must document product dispositions to be implemented to minimise risk of exposure of the consumer, for 7 failures a response team visit may ensue and for 8 failures the MPI can apply sanctions under the Animal Products Act. A Quarterly Performance Failure measure for chickens has been introduced in 2016 to provide a more risk based approach identifying poor performers ($\geq 30\%$ prevalence/quarter) who are expected to take corrective actions rather than adjusting the stringency of the *Campylobacter* Performance Target for all processors. Additional studies have been conducted at point of slaughter (reflecting farm practices/one-off studies or intermittent) and at retail (one-off studies or intermittent).

Raw milk

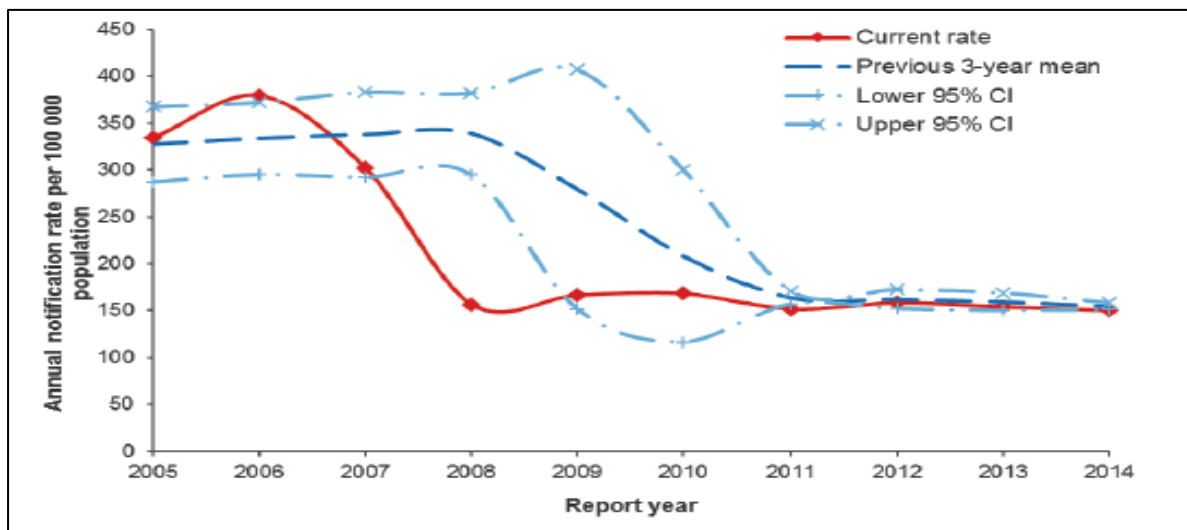
Raw milk has been implicated in campylobacteriosis outbreaks albeit with varying strength of evidence except in the sentinel site study (NZMPI, 2013a). The health risk of *Campylobacter* in untreated raw milk was modelled for sales on- and off-farm and are shown in Table 10. The prevalence of *Campylobacter* in 2 surveys of raw milk collected from bulk milk was 0.34% (2007-2008) and 0.58% (2011-2012). The prevalence of *C. jejuni* in faeces of dairy cattle, 49-54%, and typing of 30 isolates showed dominance of ruminant types associated with human illness (NZMPI, 2015a). Changes in regulations allowing raw milk sales have been described in the preceding NTS section.

Evidence for success

Campylobacteriosis incidence and outbreaks

Before 2008 NZ had the highest campylobacteriosis rate reported worldwide. The 50% reduction target set in the *Campylobacter* Risk Management Strategy was very successfully achieved, and the pattern of notifications from 2005-2014 can be seen in Figure 16. The rate of total infections in 2014 was 150.3 cases/100,00 population and those foodborne estimated to be 89.0 cases/100,00 population (61.5-116.0, 95% CrI) (Table 9). The number of foodborne outbreaks ranged from 7-16/yr. between 2007-2013. There has been a significant increase in the number of outbreak associated cases from 36-77 cases/yr. in 2007-2013 to 158 cases in 2014 due to 3 outbreaks. However, the case rate is still considered high and further risk management approaches are being investigated. The target in 2014 was to keep the incidence of NZ foodborne campylobacteriosis in a holding pattern (NZMPI, 2013b).

Figure 16 Total campylobacteriosis notification rates in New Zealand 2005-2014. Reproduction permitted with acknowledgement (NZMPI, 2015a)



Food attribution and contamination

The *Campylobacter* Risk Management Strategy has been successful with the reduction in illnesses coinciding with reductions of the bacterium in chickens. The NZMPI reports the main driver of the success has been the introduction of mandatory performance targets for *Campylobacter* in broiler meat at the end of processing in 2008 (NZMPI, 2013b). The MPI credits the processors achieving this through improving their hygienic practices during slaughter and dressing, and the use of processing aids, as well as measures taken on farm and through chain to meet the required hazard-based performance targets. Diced and minced retail chicken were sampled for *Campylobacter* in 2009 after the introduction of the mandatory performance target was introduced in 2008. The prevalence of positive samples declined from 86% in 2003-2004 to 70% in 2009 and the prevalence of samples with higher counts of $>1\log_{10}$ cfu/g declined from 8% to 3% indicating the exposure level from raw chicken decreased coinciding with the implementation of the Strategy (NZMAF, 2011).

The role of poultry as the dominant food source has been changing from 2005 and 2012 in association with the success of control measures for chicken meat although it is still important (NZMPI, 2014). Investigations of other source reservoirs such as ruminants are now included in the Strategy and further studies have been undertaken on other food sources e.g. other poultry (ducks and turkeys), uncooked retail meats, pig, and bobby calf carcasses (including AMR), pre-packaged fresh leafy salads at retail. Molecular typing has proven valuable in the studies on poultry; however, further discrimination than that provided by MLST is required with a broader focus on ruminants and other transmission pathways. The effects of the changed regulations for raw milk sales remains to be determined.

Listeria

Public health and economic burden

From 1997 to 2014, 35 listeriosis notifications (including perinatal cases) occurred in 1997 then ranged from 17-28/yr. (NZMPI, 2015a). In 2014 there was 25 listeriosis notifications, all domestic, 5 peri-natal, 5 deaths, and 0.49 illnesses/100,000 populations were estimated to be foodborne. The cost of listeriosis in NZ is estimated to be \$NZ 15.2 million that is 11% all disease specific costs in 2010 and is almost the same cost as salmonellosis (NZMPI, 2010). The highest number of illnesses, hospitalisations

and non-perinatal deaths occur in the ≥ 60 yr. age group. Underlying illnesses and taking immune-suppressive drugs have been identified as risk factors.

Serotypes and genotypes

Serotypes 4 and 1/2 have been identified among notifications. Serotype 4 isolates decreased from 72.7% to 36.8% between 2010-2013 and serotype 1/2 increased from 27.3% to 63.2% with a reversal in 2014 of 57.1% serotype O4 and 42.9% serotypes 1/2. MVLST has been used to further characterise isolates. For example, isolates from seafood processing plants and products and human cases were compared and indistinguishable types were detected in mussels and listeriosis cases (Cruz et al., 2014).

Food attribution

Foods implicated in outbreaks/clusters in the past included contaminated seafood and cooked meats and *L. monocytogenes* has been detected in surveys of cooked meats, seafood products and pasta salads (NZMPI, 2013c). The MPI has conducted risk profiles on a wide range of foods e.g. ice cream, low moisture and soft cheeses, processed RTE meats and RTE salads, and surveys e.g. RTE smoked fish and seed sprouts.

Risk management and regulatory approach

A *Listeria* Risk Management Strategy was established by the MPI and the latest update cited for 2013-2014 (NZMPI, 2013c) lists the most important risk management approaches to be those that:

- reduce the opportunity and amount of contamination of food with *L. monocytogenes*,
- minimise the potential for growth in the food, and,
- consumer communication on avoiding risky foods.

General regulatory requirements requiring GOPs and HACCP are applied to address the first dot points. Failure in the implementation of these measures by businesses has resulted in illnesses and the MPI has sought to focus on measures that are practical, feasible and cost effective in the Strategy.

The Strategy performance target baseline is the average rate for 2004-2007 of 0.45 illnesses /100,000 population (NZMPI, 2013c). The performance target set in 2014 is for no change in the incidence already achieved in 2013-2014 (NZMPI, 2015a). The MPI recognises that maintaining the status quo in the future will not be achieved without intervention due to 2 factors that could increase infection rates: the increasing aging populations including increasingly susceptible individuals and the increasing availability and consumption of RTE foods. In addition, in 2013, MPI commented that it was not known if current industry risk management was adequate or the most effective. The Strategy in 2013 was centred around these main areas:

- ensuring risk management options were effective and consistently applied,
- tracking international developments and conducting research to inform the Strategy
- maintaining communication of information to all stakeholders,
- documenting a process for monitoring and review.

RTE foods

Manufacturers of RTE products must have a written RMP documenting control measures for *L. monocytogenes* in product and the environment, testing programs, operator competencies, and these have been updated in 2016 with more specific requirements in the RMP (NZMPI, 2016e). NZ, in 2014, adopted the amendment in the FSANZ FSC 1.6.1 Microbiological Limits for Food establishing microbiological criteria at the end point of a product's shelf life for *L. monocytogenes* in all types of RTE foods based on whether growth can occur and shelf life duration. NZ MPI refers to the FSANZ requirements for date labelling of foods.

Dairy

The regulatory changes in NZ for raw milk sales and testing requirements for conformance measures have been reviewed in the NTS section and in Annex 10. The risk of listeriosis following consumption of raw milk is estimated to be low. Additional requirements have been set for dairies that supply milk for manufacture of raw milk products and a Code of Practice is provided. Some raw milk cheeses can be manufactured in NZ or imported based on their likelihood of pathogen survival or growth. Dairies that supply milk must operate under an MPI registered RMP where milk must be collected only from disease free animals under hygienic conditions and chilled at prescribed rates to target temperatures, and raw milk for manufacture of dairy products must have an APC <100,000 cfu/ml.

Stakeholder information and education

Information has been provided to consumers through the MPI webpage at <https://mpi.govt.nz/food-safety/whats-in-our-food/bacteria-and-viruses-in-food/listeria-monocytogenes/> and the Ministry of Health. Extensive information is provided to the food industry through guidance and guideline documents e.g. developing RMPs for control in RTE foods, for food service, vulnerable populations, health and residential care, for recalls, and for establishing shelf life, available through the “Industry eLibrary” cited 29/03/16 at [http://www.foodsafety.govt.nz/elibrary/search.htm?audience=industry&keywords=listeria&publication_type=.](http://www.foodsafety.govt.nz/elibrary/search.htm?audience=industry&keywords=listeria&publication_type=)

Evidence for success

Listeriosis incidence, outbreaks and food contamination

Notifications are tracked quarterly and foodborne infections have remained below the target baseline (NZMPI, 2015a). There have been 2 outbreaks since 2005, one in 2012 among hospital patients and linked with cold meats. Many surveys and studies available were undertaken a decade ago. Most of the strategic objectives over the last years has been management, risk communication and surveillance focused and have been achieved. Surveys have been conducted of individual foods although there was no baseline for comparison. Little other evidence was found to document the success of the Strategy.

Current situation NSW

Evidence of health and economic burdens of foodborne illness

Estimates of foodborne gastroenteritis are available Australia-wide, the last being prepared from data of 2006-2010 when it was estimated 4.1 million cases occurred of which about 20% were associated with known pathogens (Kirk et al., 2014). *Campylobacteriosis* was the most common bacterial cause of foodborne gastroenteritis causing 179,000 cases/yr. (108,500–290,000, 90% CrI), a rate increase of 13% since 2000, followed by salmonellosis at 39,600 cases/yr. (21,200–73,400, 90% CrI), a rate increase of 24% since 2000.

Among the national foodborne illnesses, the median percentage estimated to be foodborne were: NTS 72% (53-86, 90% CrI), and *Campylobacter* 77% (62-89, 90% CrI). Similar estimates were made using an expert elicitation process and in addition foodborne listeriosis was estimated at 98% (90-100) (Vally et al., 2014). NTS data here includes serotype Paratyphi. In NSW the cost of foodborne illness is estimated at \$375 million (NSWGov, 2015b).

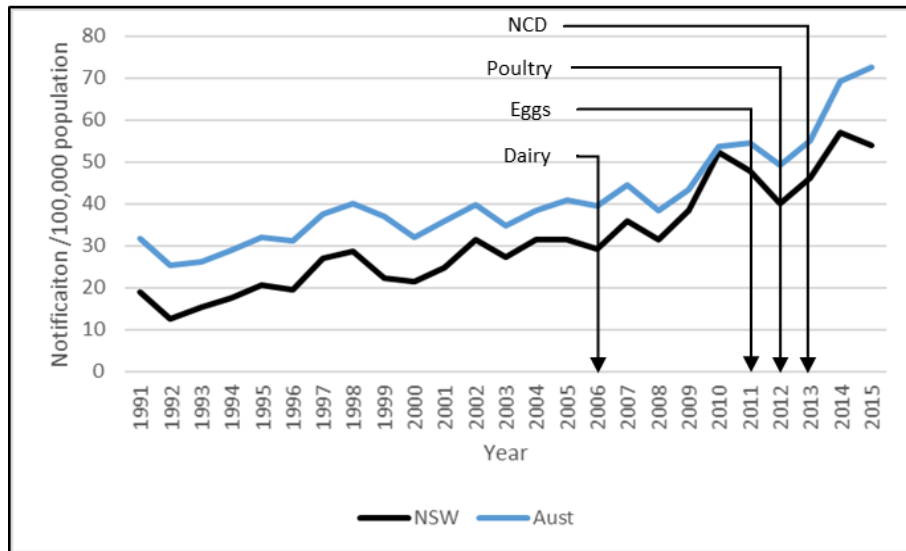


Figure 17 Notifications of salmonellosis in New South Wales and Australia to the NNDSS 1991-2015 with year of introduction of Primary Production and Processing Standards and the approximate introduction of non-culture detection(NCD) reports (NNDSS data from <http://www.health.gov.au/internet/main/publishing.nsf/Content/cda-pubs-annlrpt-ndssar.htm>, cited 20/04/2016)

Salmonellosis and listeriosis are notifiable in NSW although not campylobacteriosis except when cases are linked in clusters or outbreaks. From 1991 to 2014 there has been an increasing trend in salmonellosis notifications to the NNDSS for Australia and also NSW (Figure 17). Further annual data is required to see if the decrease in NSW beyond 2015 is continued. In Australia, the notification rate for campylobacteriosis (excluding NSW) has been trending upward since reporting in 1991 and was 131.9 notifications/100,000 population in 2015, the range among states and territories was 107.7 to 196.2 notifications /100,00 population (Figure 18). The rates began to fall in 2011 although reporting of non-culture dependent laboratory methods was introduced about that time so that the significance of the trend in 2014 and 2015 is unclear at present.

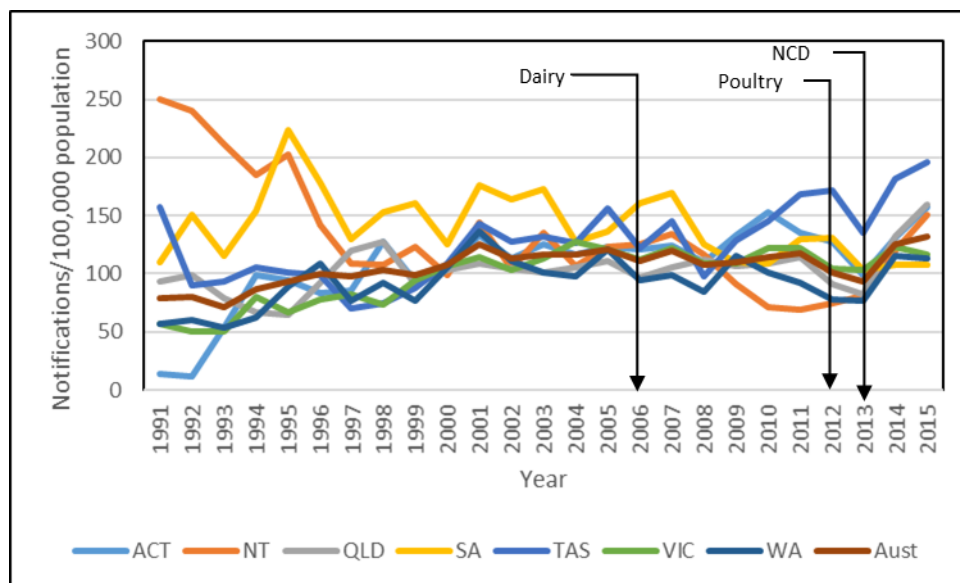


Figure 18 Notifications of campylobacteriosis for Australia and States and Territories other than New South Wales to the NNDSS 1991-2015 with year of introduction of Primary Production and Processing Standards and the approximate time of introduction of non-culture detection (NCD) reports (NNDSS data from

<http://www.health.gov.au/internet/main/publishing.nsf/Content/cda-pubs-annlrpt-nddssar.htm>, cited 20/04/2016)

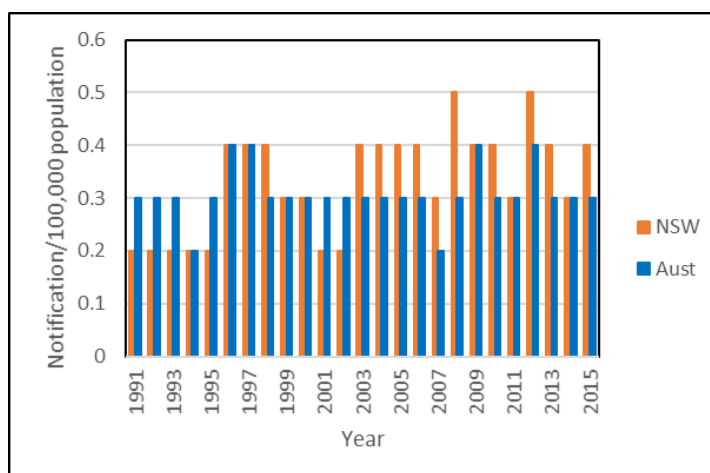


Figure 19 Notifications of listeriosis in New South Wales and Australia to the NNDSS 1991-2015 (NNDSS data from

<http://www.health.gov.au/internet/main/publishing.nsf/Content/cda-pubs-annlrpt-nddssar.htm>, cited 20/04/2016)

In 2014, the notification rate for listeriosis in NSW was 0.4 cases /100,000 population and the national rate was 0.3/100,000 population (Figure 19). The case fatality rate of listeriosis in foodborne outbreaks between 2001-2009 in Australia was 12% (Astridge et al., 2011).

NTS causes the largest proportion of foodborne outbreaks in NSW with few caused by *Campylobacter* and *L. monocytogenes* (Table 12).

Table 12 Foodborne outbreaks in NSW between 2011-2014 caused by *Salmonella*, *Campylobacter* and *L. monocytogenes*. Data from OzFoodNet NSW Annual Reports available at <http://www.health.nsw.gov.au/Infectious/foodborne/Pages/ozfoodnet-rpt.aspx>

Aetiological agent	Outbreaks (% total outbreaks)			
	2011 (n=48)	2012 (n=61)	2013 (n=39)	2014 (n=44)
<i>Salmonella</i>	16 (33)	27 (44)	12 (31)	26 (59)
<i>Campylobacter</i>	2 (4)	0 (0)	1 (2.6)	0 (0)
<i>L. monocytogenes</i>	0 (0)	0 (0)	1 (2.6)	1 (2.3)

Food attribution

No specific food source or reservoir attribution studies were identified for NSW and limited published data was found for Australia. Some evidence of food vehicles is available from outbreak investigations and case-control studies and more detailed information on specific pathogens is presented in the following pathogen sections. It is noted also that *Campylobacter* cases tend to be reported as sporadic and not identified as outbreaks so there is only limited information on this pathogen from outbreak reports. Among 1,025 Australian foodborne outbreaks between 1991-2015, a causative or suspected food was identified in 59% (Astridge et al., 2011). Those associated with the highest burden of illness were linked with eggs, chicken and poultry, vegetables and salads, and fish/seafood (6% illnesses). The foods attributed and linked with NTS and *Campylobacter* in outbreaks were as follows:

- Eggs: 7% total outbreak illnesses of which NTS caused 97%;
- Poultry meat: 8% total outbreak illnesses of which NTS caused 30%, *Campylobacter* caused 16%;
- Fresh produce: 7% outbreak illnesses of which NTS caused 30%;

- NTS outbreaks were also linked with red meat, and dishes such as condiments/sauces, desserts and sandwiches.

Food regulation

The food regulation system in Australia is a cooperative arrangement among the States and Territories and with NZ. FSANZ develops food standards and States such as NSW have their own laws to implement and enforce these standards with local governments involved in monitoring and enforcement. The NSW food industry is subject to the following requirements that are expected to have an impact on control of NTS, *Campylobacter* and *L. monocytogenes* in food:

Australia New Zealand Food Standards Code (described at the FSANZ webpage at <http://www.foodstandards.gov.au/industry/safetystandards/Pages/default.aspx>). The Code requires food businesses to produce food that is safe and suitable to eat, includes standards covering general health and hygiene obligations for food handlers, and standard operating requirements for premises and equipment. Food safety programs based on HACCP principles are required for high risk businesses. Specific standards apply for potentially hazardous food served to vulnerable persons and there are commodity based Primary Production and Processing Standards (PPPS) for seafood (PPPS 4.2.1), poultry meat (PPPS 4.2.2), meat and meat products (PPPS 4.2.3) dairy (PPPS 4.2.4), eggs and egg products (4.2.5) and seed sprouts (PPPS 4.2.6). The PPPS require implementation of documented food safety management plans. There are microbiological limits for specific foods although these are currently under review.

Food Act 2013 (NSW) brings the FSANZ Food Code into force within NSW. The Act allows the NSW FA to make regulations referred to as Food Safety Schemes. The Schemes have to be developed in consultation with industry, be risk based, can include justified national, international or other standards, and can include performance-based and prescriptive approaches.

Food Regulation 2015. The Food Regulation 2015 (NSW Gov, 2015a) underpins the regulatory work of the NSW FA and sets the minimum food safety requirements for food industry sectors that have been identified as higher risk using a priority classification system based on a food safety risk profiling framework (NSWFA, 2010). The higher risk sectors for which there are Food Safety Schemes are defined by commodity groups including meat, dairy, seafood, shellfish, plant foods, eggs, and also includes service of food for vulnerable persons. With few modifications these are based on the above national regulations with regard to food safety.

Verification and Surveillance Programs

The Food Safety Schemes Manual sets out for food businesses testing programs for commodity groups and products mandated in the Regulation (NSWFA, 2015). The tests include microbiological food safety criteria (pathogen detection or enumeration) and microbiological hygiene criteria (indicator tests for products and for other processing inputs e.g. water and environmental sampling) and process criteria are set for processes such as pasteurisation. Corrective action is not included other than in some cases notifying the NSW FA.

The Microbiological Testing Verification Program together with audits and investigation procedures are used to measure compliance of food businesses with the Food Regulation 2015 and industry performance (NSWFA, 2014a). The 2014-2015 Verification Program included meat, dairy, plant products, and seafood. It involves random sampling and testing of food manufactured or packaged under the Regulation. An egg farm and egg grading facility surveillance program commenced in 2013. The NSW FA conducts periodic surveys to inform risk managers (NSWFA, 2016).

The average rate of compliance across all industry sectors was recorded as 94% in the Food Safety Strategy 2015-2021 (NSWGov, 2015b). NSW has a Scores on Doors program where in 2014 less than 2% businesses did not meet the food safety standards at inspection.

Food Safety Strategy 2015-2021

The NSW Government has established a Food Safety Strategy 2015-2021 (NSWGov, 2015b). The goal stated is to ensure food businesses contribute to the State's economic growth and prosperity by reducing foodborne illnesses and delivering safe and superior quality food to local and international customers. This will be delivered in part by reducing foodborne illness incidents, training food retailers in safe food handling to minimise outbreaks of salmonellosis, and working with a number of sectors to ensure safe on-farm production processes. A health goal to reduce overall foodborne illness by 30% has been established.

Foodborne illness has multiple aetiologies that differ significantly so that a general quantitative reduction target of 30% becomes difficult for risk managers to implement and assess. The target will need to be further defined for reductions of specific foodborne illnesses, prioritised based on health and economic burdens for NSW and their respective health risks, so that risk management strategies can be appropriately implemented and progress quantified. Such health goals could be articulated by the NSW FA risk managers into meaningful food safety objectives and risk-based performance targets within a structured risk management framework that has been a successful approach in other countries reviewed.

The health goal of 30% reduction in foodborne illnesses is a significant advance in food safety management for the NSW FA. Further definition of specific foodborne illnesses is required to allow a targeted pathogen risk-based strategy and a structured risk management approach.

Non-typhoidal *Salmonella*

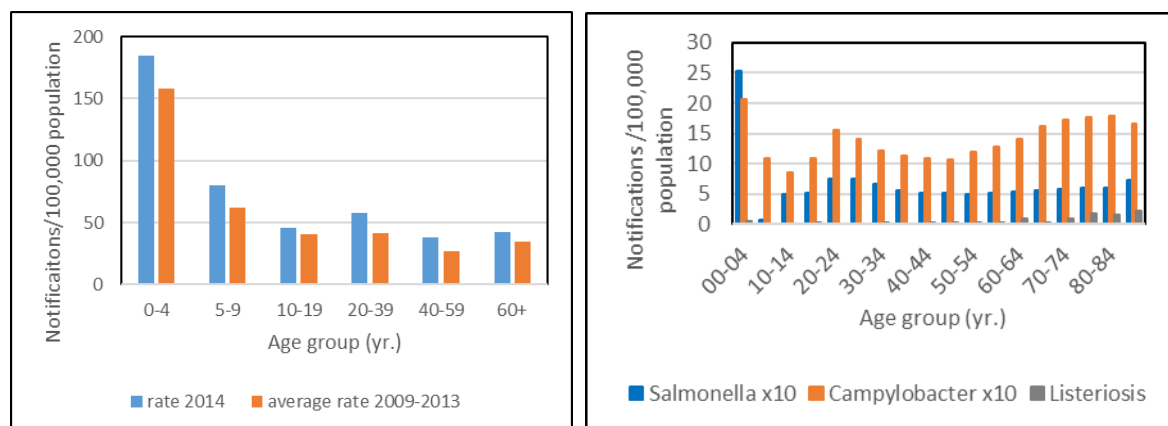
Evidence of public health and economic burden

Nationally, salmonellosis was estimated around 2010 to cause 39,600 cases/yr. (21,200–73,400, 90% CrI), 2,100 (1,300-3,00, 90% CrI) hospitalisations/yr. and 15 (8-20, 90% CrI) deaths/yr. (Kirk et al., 2014). OzFoodNet in NSW reported in 2014 there were 4,317 notifications of salmonellosis in NSW. There has been a common pattern among salmonellosis notifications with a distinct summer peak and infections occurring most frequently in the 0-4yr. age groups and a smaller peak for young adults of 20-39 yr. age (Figure 20 left graph).

Food attribution

Some evidence of NTS food source attribution in NSW can be gained from outbreak investigations reported by OzFoodNet NSW (OzFoodNet Annual Reports cited 24/04/16 at <http://www.health.nsw.gov.au/Infectious/foodborne/Pages/ozfoodnet-rpt.aspx>). Between 2011-2014, 81 of 192 (42%) outbreaks were caused by NTS, 71 (88%) of which were caused by *S. Typhimurium*. Of the 42 *S. Typhimurium* outbreaks where a food vehicle was identified, raw or partially cooked eggs were implicated in 36 (86%), including mainly raw egg based desserts (36%) and raw egg based sauces or dressings (47%). In Australia between 2001-2011, the number of NTS outbreaks increased from 1 in 5 total outbreaks in 2001 to 1 in 2 total outbreaks in 2011. Among 116 egg related outbreaks, all were caused by NTS and 90% of these were *S. Typhimurium* (Moffatt et al., 2016). The main settings for these outbreaks involved commercial food providers (61%) and private residences (28%) and the trend appears similar in NSW.

Figure 20 Left. Rate of salmonellosis cases reported in 2014 and the 2009-2013 average rate by age group in New South Wales. Data from (Ward et al., 2014). Right. Rates of salmonellosis, campylobacteriosis and listeriosis in Australia 2015 (NNDSS data from <http://www.health.gov.au/internet/main/publishing.nsf/Content/cda-pubs-annlrpt-nndssar.htm>, cited 20/04/2016)



Cross-contaminated complex foods and chicken dishes were responsible for a small number of outbreaks in NSW 2011-2014. Two chicken-related outbreaks were caused by serotype Singapore and one Typhimurium, and Muenchen was the cause of an outbreak linked with a leg of ham.

While outbreak data can be used to imply which foods are a priority caution is required. There is potential bias in outbreak investigations; for example, reports of eggs and egg-based dishes as in commercial and event settings are likely to involve larger numbers of people and are more easily recognised and investigated than sporadic cases. In 2014 OzFoodNet NSW Report, there were 4,317 reports of NTS infections and 143 cases in 9 outbreaks where egg related foods were listed as suspected/responsible vehicle with varying strengths of evidence. These cases represent 3.3% of total NTS notifications for the year. In a Bayesian source attribution study of salmonellosis in South Australia, it was estimated 35% (95% CrI: 20–49) of sporadic cases could be attributed to chicken meat and 37% (95% CrI: 23–53) of sporadic cases to eggs (Glass et al., 2016). Of outbreak-related cases for that State’s population, 33% (95% CrI: 20–62) were attributed to chicken meat and 59% (95% CrI: 29–75) to eggs. On further analysis the authors concluded there was a higher risk of illness from contaminated eggs than chicken and that consumption and handling practices played a larger role with eggs. However, both eggs and chicken were considered important vehicles of NTS infection.

NTS types

The most frequently reported NTS serotype in NSW in 2014 was Typhimurium representing 59% of all NTS notifications followed by Enteritidis (85% acquired overseas) and Virchow (Ward et al., 2014). MLVA has been used to type NTS in NSW and in 2014 there were 353 distinct MLVA types of which the top 10 represented 44% of all typed notifications.

Microbiological source attribution approaches including the use of genotyping of strains as now introduced could be used to enhance understanding of the contribution of different food sources and transmission pathways, non-food pathways, at risk groups for foodborne salmonellosis and their risk factors to ensure risk-based focus of management strategies.

Risk management and regulatory approaches

A *Salmonella* Strategy is included in the Food Safety Strategy 2015-2021 (NSWGov, 2015b). There is no link provided with evidence of expected illness reduction and quantitative performance targets for foods prioritised for this sub-strategy within the higher level Strategy as discussed above. The activities

are focused on control of shell egg contamination, microbiological monitoring, training of food retailers, and improved NTS genotyping systems. Approaches to risk management of NTS in eggs and other commodities commonly implicated in foodborne NTS transmission are discussed below.

Eggs

Based on surveillance and outbreak data in NSW, NTS, in particular *S. Typhimurium*, contamination of eggs is a food safety priority with a need to reduce the level of shell egg contamination and to improve safe handling of food prepared from shell eggs before consumption.

FSANZ on its website (cited 04/05/16

<http://www.foodstandards.gov.au/code/primaryproduction/egg/pages/default.aspx>) states the PPPS 4.2.5 Eggs 2011 will reduce the incidence of illness associated with eggs by:

- legally requiring egg producers and processors to identify and control safety hazards, such as ensuring feed is not contaminated,
- prohibiting the sale of cracked and dirty eggs unless they are sold to a processor for pasteurization,
- requiring individual eggs to be stamped with the producers' unique identification so they can be traced.

Other parts of the Food Code require general health, hygiene and hazard controls at food production and handling and prohibit the sale of cracked and dirty eggs.

The NSW Egg Food Safety Scheme was introduced in 2010 and incorporates much of the PPPS 4.2.5 (NSWFA, 2013). The Scheme covers businesses producing, grading, or processing eggs and eggs products for sale above minimum production limits and requires control of hazards including NTS. Preceding this a qualitative risk assessment was undertaken that identified important control measures that included biosecurity on farm, management of the supply chain conditions, prohibition of sale of cracked eggs, use of pasteurised egg products, and safe food preparation for vulnerable groups (NSWFA, 2009). Biosecurity measures are not mandated in the PPPS although expected to be implemented. Essential control measures identified by the NSW FA although not all mandated included:

- A documented food safety program including hazard control and basic health and hygiene;
- Biosecurity measures implemented; environmental surveillance; pest control; SE monitoring program;
- Drinking water monitoring using *E. coli* and coliform counts; stock food control, hygiene and traceback; control of pesticides and veterinary medicines;
- Litter control, cleanout between laying cycles;
- Hygienic egg collection; egg stamping for traceability; storage (<15°C, eggs supplied within 96 hr. of lay or equivalent);
- Cracked and dirty shell eggs must not be made available for retail sale or catering purposes; dirty eggs dry-cleaned; ungraded eggs stored at ≤8°C;
- Processed eggs must be pasteurised according to defined process criteria or treated with a validated equivalent treatment.

The Australian Egg Corporation Ltd has evaluated the use of live and inactivated vaccines for efficacy against infection with NTS serotypes Typhimurium, Infantis and Virchow as a potential flock level intervention (AECL Project No. 1US091. Cited 26/04/16 at <https://www.aecl.org/assets/RD-files/Outputs-2/1US091B-Summary.pdf>). The vaccines were promising although need for further work was indicated.

Sampling programs are required by licenced egg processing businesses according to the Food Safety Schemes Manual (NSWFA, 2015). This includes NTS food safety criteria for egg products, hygiene criteria for water used in processing and process criteria for pasteurisation. There are no health goals for shell eggs or performance targets for egg producers to guide their mandatory food safety plans and for regulatory verification and monitoring, other than comparison with a baseline figure.

There are no targeted health goals for salmonellosis and egg contamination. Food safety objectives to guide mandatory food safety plans and for regulatory verification and monitoring are established for egg processing and could be considered for shell egg production.

A baseline evaluation was undertaken in NSW in 2011-2012 for the Egg Food Safety Scheme. About 2/3 of 49 egg farm systems were free-range and a quarter cage-based, each sector producing about half the state's egg production each. A small proportion were barn housed. From a food safety perspective, farm inputs, biosecurity, crack detection practices, egg cleaning, and carton labelling for traceability, were flagged as control points for further improvement. One third of businesses used wet-washing to clean eggs and improved water wash hygiene and monitoring were identified as requiring improvement. In the baseline microbiological survey, NTS were detected on 22 of 49 farms, 20% were serotype Typhimurium and no serotype Enteritidis was detected (Figure 21). NTS was detected in half the sheds and in only one third housing single aged flocks. It was estimated less than 100 eggs of a possible 2.5 million produced each day may be contaminated with NTS.

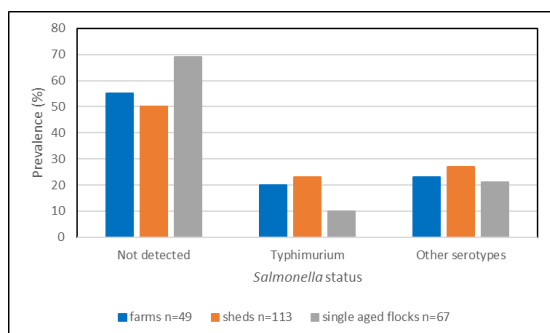


Figure 21 Baseline prevalence of *Salmonella* on farms in NSW 2011-2012 (NSWFA, 2013)

Typhimurium and other NTS serotypes were detected in 0% and 11% of 27 bulk stock feeds and 1% and 16% stock feeds at point of consumption, 4 % and 2% of 46 hen drinking water samples, 10% and 17% of 99 boot/cage swabs, 9% and 8% faecal material and no drinking water samples respectively. 17 NTS serotypes were detected on farms, Typhimurium and Infantis were the most common and 4 of the 6 most common Typhimurium phage types were also common human types.

Subsequently, egg producers, including those with additional activity, have been included in the Verification and Surveillance Program (NSWFA, 2014a). This is a random sampling program conducted by regulatory officers. Samples are collected from each farm shed including environmental samples (stock feed, boot swabs and faeces) and one dozen of ungraded eggs. For any larger egg farm, a maximum of 4 sheds are randomly selected for sampling. Additional activity such as the egg grading facility and practices are also assessed. All samples are tested for NTS only. Positive results are followed up by FSA Officers to initiate remedial action and re-testing or enforcement action as appropriate.

Targeting "regulated" serotypes could be considered in mandatory testing with appropriate actions to prevent the entry of shell eggs contaminated with these types into the marketplace.

Food handler and consumer food handling

Safe handling of eggs is addressed at both the food retailer/handler and consumer sectors of the egg supply chain by the NSW FA. There are online education materials provided for those involved in the egg food chain, industry guidelines, and consumer education materials.

From September 2015, for food safety supervisors in hospitality and retail food service to be certified for a food premise in NSW, and for a valid certificate to be issued, they must have attained required units of competency from an approved registered training organisation in safe egg handling, allergen management, and cleaning and sanitising practices, renewed each 5 yr. (See <http://www.foodauthority.nsw.gov.au/rp/fss-food-safety-supervisors/training-for-food-handlers>, cited 04/05/16).

In 2011, 107 samples of raw egg dishes/products were surveyed from 46 premises in the City of Sydney. NTS was not detected although a Caesar dressing was classified as potentially hazardous due to high *Bacillus cereus* counts and 13 classified unsatisfactory due to high APC and/or moderate levels of *B. cereus*. Observations and questionnaires were used to survey preparation, cleaning, sanitation and egg quality from 44 premises. Of these 23% of premises had cracked and dirty eggs in storage and there was a lack of knowledge regarding the risks involved in their use.

The majority of businesses surveyed were found to require improvement in:

- temperature control of raw egg products during and in between use,
- date coding of final products containing raw egg, and,
- egg separation techniques during processing to prevent cross contamination.

It is proposed in the Food Safety Strategy 2015-2021 to improve training of food safety supervisors and of food retailers in safe food handling to minimise outbreaks of salmonellosis (NSWGov, 2015b). Food retailers handling raw egg products are specifically targeted.

Control measures have been initiated at the food service, consumer sector of the egg supply chain. It is too early to comment on progress.

Meat and Poultry

The Meat Food Safety Scheme incorporates the PPPS 4.2.2 Poultry and 4.2.3 Meat and various Australian standards for hygiene in meat processing plants, transport, for rendering and pet food, and includes all meat species both farmed and wild caught. PPPS 4.2.3 for meat requires traceability from primary production, it recognises Australian Standards for hygienic production of meats. It includes specific requirements for HACCP based controls for RTE meats that have end product microbiological criteria and process criteria for uncooked comminuted fermented meats. A documented food safety program is required. Red meat abattoirs have been required to implement HACCP based food safety programs since 1997 and to carry out microbiological testing of carcasses since 1998. Abattoirs registered for meat export have to comply with requirements of the Australian Government and importing countries some of which have stringent requirements e.g. USA. Fresh red meat is considered to present a low risk, particularly when compared with chicken meat. However, it should not be ignored if trends for eating undercooked ground or non-intact products is increasing as reported anecdotally. There are limited reports of the rate of NTS detection in ground meats and those identified were higher than on carcasses e.g. ground beef 1.1% (MLA, undated) and ground pork 1.1% (Hamilton et al., 2011). In the updated risk assessment, awareness was drawn to potential emerging hazardous situations with changing food preparations and consumer choices such as consumption of rare cooked meat, limited inactivation of pathogens following internalisation with meat and poultry

tenderisation and marination, and consumption of undercooked offal (e.g. chicken livers). *L. monocytogenes* has been a concern in RTE meats.

Control of pathogen transmission via poultry meat has been a focus of food safety concern among fresh meats in NSW for some time (NSWFA, 2009). A survey of NTS and chicken carcasses at the end of chilling at NSW slaughter plants was conducted by the NSW FA in 2004/2005 in response to an increase in a particular serotype Typhimurium DT 170 in human salmonellosis cases (Fabiansson, 2005). In an exploratory survey in 2004, at least one in 5 carcasses was positive in 100% of 25 consignments from 9 plants with 5 (20%) positive for *S. Sofia* only. Of the carcasses, 191 of 205 (93%) were NTS positive with 95 (46%) positive only for *S. Sofia*. After working with industry to improve NTS control, a repeat survey was conducted in 10 plants in 2015 with improved results. At least one in 5 carcasses in 35 out of 40 consignments (88%) was positive with 17/40 (43%) only positive for *S. Sofia*, and 124/200 (62%) carcasses were positive, 42% only carrying *S. Sofia*. After adjusting the data, it was estimated a possible 59% prevalence of NTS and 21% prevalence excluding *Sofia* only positives occurred across the NSW industry. In 2005, the mean concentration of NTS on positive carcasses was 0.33 cfu/cm² or -0.48 log₁₀/cm² (range -2.0 - 0.38 log₁₀/cm²). Prevalence and concentration varied between plants and within plant consignments.

The PPPS 4.2.2 for poultry meat was introduced in 2012 and requires producers and processors to document and apply a food safety plan with evidence of identification of hazards and implementation of control measures for identified hazards. The latter is interpreted to include reduction of pathogens; however, there are no performance measures or targets associated with the PPPS. A baseline was reported for NTS and *Campylobacter* by FSANZ in 2008 and included data for NSW following processing in 2008 and NSW data from retail sampling in the preceding years 2005-2006 was reported separately (FSANZ, 2010; Pointon et al., 2008). The results are shown in Table 13. NTS was detected in about half of the samples in each study. Of the carcass samples 28.5% were positive for *S. Sofia* and of the NTS isolates from retail samples 35.3% were serotype *Sofia*. It is not clear from the reports if the percentage *Sofia* positive samples include those with *Sofia* only or also *Sofia* and other serotype positive samples. A small study of 99 organic chicken samples at retail was conducted by the NSW FA in 2005 where the prevalence was 63.6%, slightly higher than the large survey and with 11.6% samples *Sofia* only positive (NSW FA pers. comm.).

No statement was found that the baseline levels are related to an acceptable level of consumer protection from eating poultry meats nationally or in NSW although they seem to be widely applied as an acceptance measure and for comparative purposes over time.

Table 13 Baseline prevalence and concentration of total *Salmonella* and *Campylobacter* in chicken meat in New South Wales at retail in 2005-2006 Pointon et al., 2008) and post-processing in 2008 (FSANZ, 2010)

Site of sampling	Total <i>Salmonella</i>		<i>Campylobacter</i>	
	Prevalence % positive (95%CI)	Concentration Mean log (SD)/cm ²	Prevalence % positive (95%CI)	Concentration Mean log (SD)/cm ²
Post-processing carcasses in 2008 (n=246)	48.4 (42.0-54.8)	-1.9 (0.03)	95.1 (91.6-97.5)	0.73 (0.03) or 4.07(0.05)/1.78kg carcase)
Retail carcasses and pieces in 2005-2006 (n=549)	47.7	-1.42 (0.6)	87.8	0.87 (0.45)

The poultry meat NSW Verification Program includes random collection of samples and testing for indicators of process performance by testing for APC, *E. coli*, NTS and *Campylobacter* and results are compared with the 2008 baseline. The SPC results are analysed against the Australian Standard Guidelines – AS 4465:2001 (Standards Australia, 2001), which classify counts of > 500,000 cfu/cm² as marginal and >1,500,000 cfu/cm² as poor. *E. coli* counts are classified as <10 cfu/cm² excellent, between 10 – 100 good, between 100 – 1,000 acceptable and >1,000 an action level (NSW FA pers. comm.). Many of the samples from 2014-2016 were collected at retail outlets restricted to the Sydney area and some processors were interstate.

A Key Food Safety Indicator Program has also been initiated with a pilot program in 2014 to implement a simpler verification system at the farm level which reduces the audit burden on producers (Cited 23/05/16 at Foodwise March 2015, http://www.foodauthority.nsw.gov.au/_Documents/newsletters/foodwise_issue_37_2015.pdf). The large poultry processors in NSW were asked to voluntarily submit data each month on farmer declarations (time off feed); microbiological food safety testing of carcasses (NTS and *Campylobacter* presence/absence and counts); and processing parameters of chlorine and pH levels in the spin chiller. This will generate significantly more information than the poultry meat NSW Verification Program although requires all processors to participate to avoid bias.

Dairy

Regulation for the dairy industry has been in place for a long time in NSW and HACCP based food safety management programs have been required along the supply chain. The Food Code PPPS 4.2.4 introduced in 2006 is enforced. Current management practices required of the dairy industry include:

- control animal health,
- adherence to good milking practices,
- effective heat treatment (e.g. pasteurisation), and,
- controls to prevent post-pasteurisation contamination in the dairy processing environment.

In the Dairy food safety scheme licenced dairy businesses are required to sample and analyse products with food safety criteria and process criteria for processed products. For unpasteurised goat milk for human consumption testing for NTS, *Campylobacter* and *L. monocytogenes*, is required and the limits are pathogens not detected in 25ml samples and *E. coli* counts ≤ 3 cfu/ml in samples collected from every 20 batches (NSWFA, 2015). NTS not detected in 25g samples is also required in a range of dairy products with varying stringency based on batch numbers, as well as hygiene monitoring of any non-reticulated water source.

The highest risk of NTS infections among dairy products are consumption of milk and milk products that have not been subjected to pasteurisation or an equivalent process to inactivate pathogens (NSWFA, 2009).

Produce

Five plant product groups were identified as high risk in NSW: fresh cut fruits and vegetables usually consumed raw, vegetables-in-oil, unpasteurised juice, and seed sprouts. Businesses producing these high risk products have been required to have HACCP based food safety programs since 2005. At the time, a benchmark survey was undertaken of these businesses that indicated some premises were HACCP ready while others were not and 65-78% were compliant (Poster cited 28/04/16 at http://www.foodauthority.nsw.gov.au/_Documents/scienceandtechnical/plant_poster.pdf). The main concerns were associated with SOPs, and 7% sprouts and 5% fresh-cut fruits and vegetables had marginal hygiene indicator levels when tested.

According to the Food Safety Scheme Manual, licenced plant product businesses must test fresh cut fruits and vegetables for the presence of NTS and *L. monocytogenes* (NSWFA, 2015). It is noted that for fresh and fresh-cut fruits and vegetables NTS detection is not usually recommended for distinguishing safe and unsafe products due to their low frequency and the use of appropriate hygiene indicator organisms, process criteria, and environmental sampling may be more effective for process monitoring (ICMSF, 2011).

FSANZ commissioned a survey of national fresh horticulture products in 2005-2007 (FSANZ, 2009). The sample sizes for individual products were not large given the likelihood of pathogen detection in these types of product and they were not identified by location; nonetheless NTS was isolated from 1 of 105 strawberry samples. Also STEC O157 was detected 1/27 seed sprouts and 1/9 parsley samples and 24/369 samples had an *E. coli* Most Probable Number > 3 cfu/g, all of which indicate possible faecal contamination. Plant products are included in the Food Safety Scheme Verification Program.

In the Food Safety Strategy 2015-2021 the NSW FA will work with the Fresh Produce Safety Centre and Horticulture Innovation Australia to better identify on-farm issues and develop horticultural guidelines with the aim to ensure the safety of fresh produce. Small businesses such as market gardens will be included.

A survey of cut melons at retail was undertaken to inform NSW FA risk managers of the microbiological quality in view of international and local incidents. Microbiological analyses of 191 cut surfaces of melons and other fruits, product parameters, and storage conditions were surveyed in 45 greengrocers and supermarkets in 2015. The samples all had intrinsic properties that classified them as potentially hazardous. No NTS was detected, *L. monocytogenes* was detected in a cut honeydew and one cut watermelon had an *E. coli* count of 1,100cfu/g. APCs were in the range of 3-5 log₁₀ cfu/g for 63% and 7% were about 7 log₁₀ cfu/g. It was concluded while the overall results were very good, improvements were required in management of SOPs and minimising time on display and refrigeration should be encouraged.

Food sources other than eggs appear to present comparatively less health risk of salmonellosis based on current epidemiological evidence and testing programs. These programs can provide only limited information on NTS source attribution and the role of food vehicles for sporadic cases.

Microbiological monitoring programs are an important initiative. At present they appear random, limited in sampling plans and dependent on available resources. Regular testing by industry at control points against defined targets using appropriate sampling plans would provide an enhanced measure of performance and contamination of the food supply.

Proactive management of fresh produce is warranted given potential increased consumer exposure and changes in production practices and retailing to meet demands.

Evidence for success

Salmonellosis incidence and outbreaks

The incidence of salmonellosis in NSW appears to have reached a peak in 2014 with 57.1 notifications/100,000 population followed by a rate of 53.9 notifications /100,000 population in 2015 (Figure 17). In 2014, 4,317 cases were recorded that was a 32% increase on the annual average notifications for the previous 5 yr., a 20% increase compared with 2013 and the highest ever reported in NSW (Ward et al., 2014). Further data will be required to see if the downturn is continued and the impact of non-culture detection methods when used.

The proportion of outbreaks (n=192) from 2011-2014 caused by NTS has increased from 33 to 59% and in each year 75-100% were serotype Typhimurium and were mainly linked with raw or undercooked dishes containing egg. This has led to an ongoing focus on NTS and eggs as a priority issue in persons exposed to these products. However, the NTS foodborne and egg-related outbreaks accounted for only 8.4% and 3.3% respectively of 4,317 notifications in 2014, indicating further understanding of transmission pathways, at risk groups and risk factors are required.

Food contamination

From July 2009 to June 2014, 1,271 RTE foods were tested under the Verification and Surveillance Program (NSWFA, 2014a). NTS detections were reported from environmental samples from egg farms and grading facilities. This has to be considered in context as farm environments are more likely to yield positive results than products.

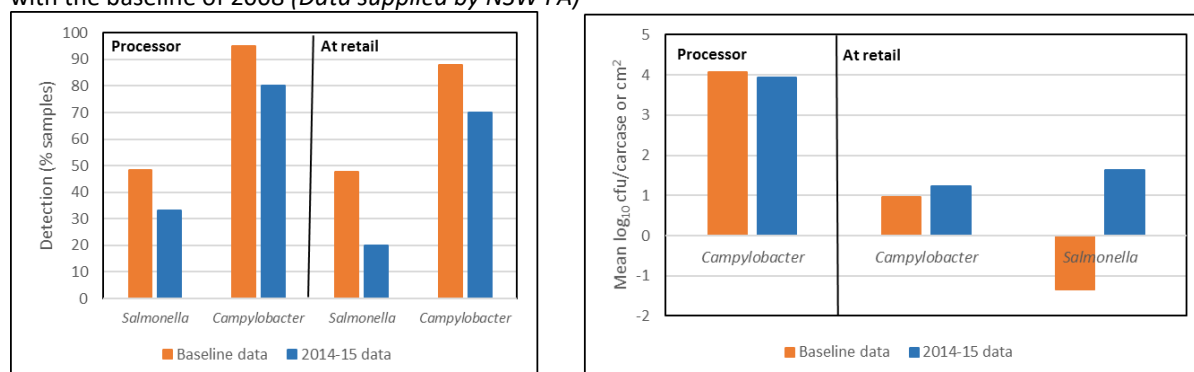
Eggs. The egg farm and egg grading facility Surveillance Program commenced in July 2013 (NSWFA, 2014b). In preliminary data from 2012 to 2014, no NTS was detected in 29 egg contents and on 51 egg shell surfaces, in 28 stock feed samples from 6 egg farms, and at 3 grading facilities. All 6 egg farms and 2 of 3 grading facilities had a least one environmental sample positive. The small number of egg samples had a low chance of detecting egg contamination given the estimate in the baseline study, 2011-2012, of 100 eggs of a possible 2.5 million/day may be contaminated with NTS. This data does not allow comparison with the baseline where half of 49 farms were positive. Typhimurium (36% of 25 samples) singly or with other serotypes was the most common serotype detected.

In the Annual Report for 2014-2015, 47 environmental (boot sock, stock feed and faecal) and egg samples were collected from 2 businesses and NTS was detected in 8 samples from one business (NSWFA, 2016). The number of samples in the reports is too small and random to interpret trends.

The monitoring of eggs and egg production environments is limited by the number of samples able to be tested to date. Regular industry monitoring programs including sampling plans with appropriate stringency, defined corrective actions and risk/evidence based frequency would provide an improved risk management approach.

Poultry. In the Process Verification Monitoring for poultry meat, 2014-2015, 255 samples (46 at processors, 209 at retail) were tested and the results were encouraging as the NTS detection rate was 33% overall for chicken carcasses at processors and 20% for portions with skin on and off at retail, that were a third and half of the levels in the 2008 baseline respectively (Figure 22). Counts of NTS on chicken portions at retail were higher than the baseline, -1.34 vs 1.63 log₁₀ (43 cfu/cm²) (Figure 22). Fifteen serotypes were isolated of which the following were the top 4: Abortusovis 12, Sofia 9, Agona 4 and Typhimurium 3. The higher proportion of these were not associated with human infections.

Figure 22 Process verification monitoring including detection (left graph) and enumeration (right graph) of *Salmonella* and *Campylobacter* in poultry carcasses at processors and portions at retail 2014-2015 compared with the baseline of 2008 (Data supplied by NSW FA)



A summary of the results on a slightly larger sample size of chicken portions (n=352) and some of the different portion types tested between January 2015 and April 2016 is shown in Figure 23. The NTS rate on carcasses at processors has further decreased although the rate for portions is again unchanged and varies slightly between portion types.

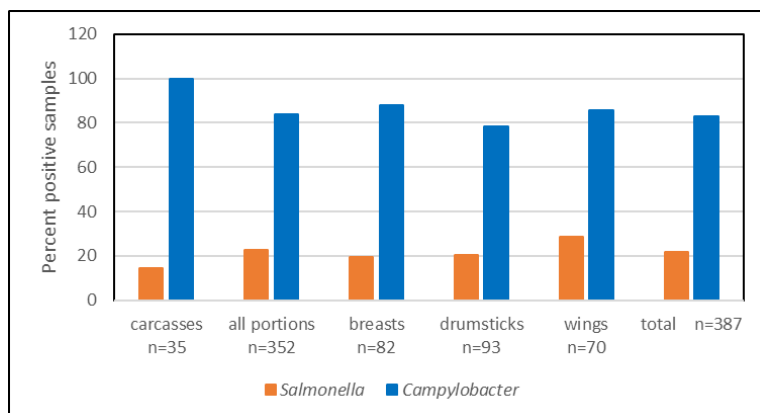


Figure 23 Process verification monitoring including detection of *Salmonella* and *Campylobacter* in poultry carcasses at processors and portions at retail January 2015 to April 2016. (Data supplied by NSW FA).

The prevalence of NTS on chicken carcasses and portions in 2014-2016 has decreased against the 2008 baseline. However, the NTS concentrations on retail portions has increased and could increase consumer exposure.

Other foods. In the Verification and Surveillance Program 2009-2014, in foods other than those reviewed above, NTS was not detected although some samples failed due to faecal indicator levels indicating ongoing need for improved hygiene (NSWFA, 2014b).

Of 401 dairy products sampled, 12 cheeses, a dairy dessert, a dairy-based dip, and a cream sample contained high levels of *E. coli*, ranging from 9 to 4,600 cfu/g. Two cheese samples contained high levels of *E. coli*, > 11,000 cfu/g and 23 cfu/g, together with coagulase positive staphylococci. These results were apparently higher than for 2006-2009/2010. In the Food Safety Scheme Verification Program from June 2014 to June 2015, 54 dairy products were tested and of these only 2 of 7 unpasteurised goat milk samples were non-compliant (NSWFA, 2016). In 2014, an outbreak caused *S. Typhimurium* involving 20 people in NSW was linked with chocolate milk although the contamination was reported to have occurred during preparation of the drink and not originated from the milk source (Ward et al., 2014).

In 2009-2014, of 471 RTE meats, poultry and pate samples, 5 had elevated levels of *E. coli* of 4-43 cfu/g (NSWFA, 2014b). No NTS was detected and 8 were contaminated with *L. monocytogenes*. The microbiological quality of uncooked fermented meats has greatly improved since the introduction of regulations in the early 2000s with all 64 samples complying in 2009-2014.

A small number of 99 plant product samples were tested, 2009-2014. Fresh cuts (37) and unpasteurised juices (12) were compliant and 4 of 50 sprout samples were non-compliant due to elevated *E. coli* levels, 23-9,300 cfu/g. From June 2014 to June 2015, 55 samples including fresh cut fruits and vegetables, seed sprouts, unpasteurised juice and others were found to be compliant although the microbiological tests were not stated (NSWFA, 2016). This number of samples is very small for pathogen detection testing of routine products of this type with low and non-homogeneous distribution of contaminants.

Management of hygiene requires ongoing improvement for all commodities. Epidemiological surveillance and investigation and food source attribution studies would provide improved knowledge of the importance of these transmission pathways for pathogens.

Gaps and opportunities

In the 3 countries and the CAC reviewed, they have progressively built on and refined their risk reduction approaches in response to the success achieved in reducing human health risk. These began with risk reduction approaches that were primarily hazard control and hygiene programs, these were expanded to include commodity specific programs and most recently they have expanded to include targeted pathogen specific or pathogen-commodity specific approaches. The latter are based on sound epidemiological and food attribution evidence, risk analysis and include use of food safety risk metrics as management tools. The Australian experience is not much different and it has moved through the first 2 stages and similarly foodborne illnesses, particularly those caused by zoonotic foodborne pathogens, remain uncontrolled to date.

Experience in other countries indicates for control of illness caused by a specific pathogen a targeted approach with health goals set and following a structured risk management framework offers the best opportunity for success. This is ideally led by a committed and responsible oversight group and includes the use of performance targets and food safety metrics to guide industry and regulatory oversight. The NSW FA has embarked on elements of this approach; however, a more focused effort may achieve greater success. This applies to each of the pathogens the NSW FA identified as of concern.

Control of NTS in the UK/EU and the USA was largely driven by serious foodborne epidemics caused by a specific serotype, SE, that became endemic in poultry flocks and was predominantly transmitted by eggs and to a much lesser extent chicken meat. This focused pathogen-pathway was a different scenario to NSW although there are parallels and as the SE epidemics have waned these countries' experiences of NTS epidemiology is more similar. The NSW FA has initiated a pathogen specific approach for NTS that focuses mainly on eggs.

NTS and egg and egg dishes are recognised as priority food safety concern. Other potential vehicles of NTS transmission seem of lower comparative importance although this assumption appears based on outbreak data and there is the potential for some bias. Further study of food source and reservoir attribution is required to determine the importance of other foodborne pathways of transmission, especially for non-outbreak cases, if the overall foodborne salmonellosis health burden is to be reduced. Further development of genomic typing, as included in the 2015-2021 strategy, should assist in investigation of case notifications to identify possible links with other cases and improve knowledge of at risk groups, food or reservoir sources, and food chain and consumer practices. Based on the outcomes, options include setting industry performance targets as well as risk based testing programs for high risk foods as occurs in other countries. A more risk based approach could result from focusing on commodities presenting highest risk as they are available in the marketplace where they provide the greatest level of exposure. For example, the USA has changed focus for PSs from poultry carcasses to portioned and minced meats and poultry, and the EU sets NTS testing and stringency for meat depending on the intended use e.g. eaten cooked or raw.

There is a gap in knowledge of food source and reservoir attribution in many of the salmonellosis infections. An opportunity for the NSW FA is to extend the objectives of the Food Safety Strategy 2015-2021 and the sub-Strategy for NTS and strain genotyping to obtain clarity on the role of food in salmonellosis transmission in outbreak and non-outbreak cases. The results could be applied in a more structured and quantifiable approach as in a CAC risk management framework.

Eggs. Quantitative risk assessments of eggs and egg products have been undertaken to inform industry and FSANZ risk managers on risk reduction options (NSWFA, 2009). They commenced at the point of lay as prior on farm factors were identified to be multi-factorial and there was a lack of quantitative data. Thomas *et al* (2006) concluded there was probably little producers and processors could do to reduce the risk of contamination of eggs at this point (Thomas et al., 2006). The approach in the PPPS has been to give industry responsibility to identify and control hazards, prohibit sale of cracked and dirty eggs, and to ensure traceability if something goes wrong. The NSW Egg Food Safety Scheme adds further and more specific guidelines. In the periodic review of the Egg Food Safety Scheme risk assessment, it was noted the implied prevalence of NTS in Australian eggs had increased since the initial assessments and that salmonellosis and NTS egg related outbreaks continue to occur and have even increased in occurrence (NSWFA, undated). This suggests some more targeted intervention and defined risk management approach is required pre- as well as post-harvest underpinned by risk assessments incorporating all the data required through chain.

Other observations now also contradict earlier assessments. Thomas *et al* (2006) stated that, in general, NTS serotypes from Australian commercial layers and their environment were not the same as those from human illness, including those linked with eggs, although, they mentioned Typhimurium was isolated from non-commercial farms and back-yard operations. If their layer data was based on clinical veterinary isolates, then this data could have been representative of primarily poultry disease strains and not human illness strains. They indicated NTS serotypes were reflective of feed contamination and environmental contamination was transient. This is contradicted in the NSW FA surveys of egg farms in 2011-2012, as Typhimurium was the most frequently isolated serotype and MLVA typing demonstrated there were common strains from farm samples and human cases (NSWFA, 2013). In the farm surveillance program since 2013, Typhimurium was detected in 36% of 26 positive samples with lower numbers of other serotypes also reported in human infections. The genotype relationship between strains was not stated. Source and reservoir attribution studies including strain genotyping now used in NSW would assist in more specifically identifying the nature of transmission pathways for human infections and risk factors through chain.

While allowing industry flexibility to decide on its own approach to controlling hazards may be desirable, there are no health goals set by regulatory risk managers or objectives by which industry can structure their choice of risk management approach for the production of shell eggs or that are influential drivers for change. This is in contrast to the approach of the USA, NZ and the EU where health goals were set for priority NTS types and risk assessments used to identify risk management options along the chain resulting in the highest risk reduction impact and the expected level of risk reduction at these points. The outcomes were articulated as quantitative performance targets to guide and incentivise industry and for regulatory verification and monitoring. As an example, in an SE epidemic setting, SE flock prevalence was related to egg contamination and health risk, therefore health goals were set, prevalence targets were established for individual flock types to achieve the goals, with mandatory testing and corrective actions that have included different combinations of

slaughter, diversion of eggs, investigation and remedial action, and retest programs. The application of food safety risk metrics tailored to local NSW settings for NTS in shell eggs would be appropriate.

The USA and UK/EU have until recently been focused on reducing the risk of SE transmitted by eggs and their approaches are often dismissed in Australia as we do not have endemic SE in poultry (See previous sections). Their risk reduction approaches begin on farm with a top down control in flocks, prevention of egg contamination together with control of bacterial growth in eggs through the food chain. It is noted that as SE has been successfully brought under control other serotypes have assumed a higher importance among NTS types. The EU now includes “regulated” serotypes that are those of most importance for human health, e.g. SE and Typhimurium and these strains are not all vertically transmitted so that some of their approaches are no longer so dissimilar. Similarly, it might be assumed as NTS strain types are dynamic, elimination of one such as serotype Typhimurium in NSW may lead to succession of others unless effective risk management frameworks are in place.

The Australian Egg Corporation Ltd (AECL) has commenced a *Salmonella* Initiative (Cited 17.05.16 at <https://www.aecl.org/resources/food-safety>). They state the presence of NTS through chain is influenced by many variables and there is no single control measure to ensure the safety of eggs. Through engagement with stakeholders the AECL’s stated aim is to allow individual stakeholders to identify the risks and to implement control measures appropriate to their sector of the supply chain. Other countries generally consider combinations and not a single control are required for greatest risk reductions at the point of consumption and this is managed in a co-ordinated manner through chain. From this Initiative to date, the AECL has identified a need for greater education on risk for all involved through chain, more formal traceback identifications, and cross-jurisdictional collaborations. An output of the initiative is a through chain risk identification report that provides a very extensive reference on regulations, hazards and controls for those involved in the egg supply chain that should be of significant value to HACCP managers (Hewson and Chia, 2016). This activity is industry focused and unfortunately does not make a connection between controls and health risk or measurable targets for risk managers.

In the Food Safety Strategy 2015-2021, the NSW FA in partnership with the AECL will research, under experimental conditions, the effectiveness of potential on farm interventions to lower the risk of NTS in and on eggs. These include vaccination, adding organic acid to feeds, control of litter and identification of bird stress. A prospective study of NTS in laying hens, both free-range and conventional, from day old chicks to the end of lay will be conducted to identify SOPs for egg farmers. This will help provide data required to more effectively undertake a true through chain risk assessment as mentioned above. The prospective study could begin at the top of the layer production pyramid and be combined with food source and reservoir attribution studies with genomic strain tracking thereby providing more accurate understanding of transmission pathways from farm to consumer. Comprehensive genomic characterisation of the types of NTS in layers, eggs and the environment and human infections will allow consideration of the EU approach to target NTS of highest priority in human health and not quantify those of low or no risk.

A better understanding of NTS transmission pathways in eggs and egg products through the entire chain will help to identify targeted and risk-based interventions at points providing the most impact on risk reduction. Research and epidemiological activities described in the Food Safety Strategy 2015-2021 and industry initiatives will contribute to this.

Further opportunities include food source and reservoir attribution studies with genotyping of strains from farm to consumption combined with risk assessment.

Setting performance targets for “regulated” NTS serotypes/genotypes that are a priority health risk and using sampling plans of appropriate stringency at strategic monitoring points would

provide guidance for HACCP managers and incentives for industry, and performance monitoring on a much larger scale for the NSW FA.

Poultry. The Poultry Verification Program can provide limited information using random sampling over limited geographical areas. Industry monitoring using appropriate sampling plans to meet expected performance levels related to risk would greatly enhance knowledge and confidence in pathogen management. In the report of 2014/2015 there was a trend for chicken portions at retail to be less frequently contaminated than carcasses at processors although portions had higher levels of contamination than in the baseline study (Figure 22). In 2015-2016 to date the trend in prevalence has changed with portions having slightly higher detection rates (Figure 23). This may be a sampling effect and larger sample numbers are required. An increase in contamination of chicken pieces after fabrication was an observation in the USA and resulted in changes in process verification programs to be more risk based and in the PSs required to meet health targets. This trend could be followed also and investigated to ensure risk based verification programs, to consider performance targets, HACCP controls and audits.

Setting performance targets and defined sampling plans at control points through chain related to risk control would provide greater evidence of performance and progress in NTS risk reduction.

Process verification data of NTS in chicken carcasses and portions could be analysed to ensure the program is risk based and to establish appropriate performance targets required to reduce chicken-meat related salmonellosis to an acceptable level.

Campylobacter

Evidence of public health and economic burden

Campylobacteriosis is not a notifiable disease in NSW. This precludes establishing a target for illness reduction and food safety objectives that are based on reduction of health risk. It also means measures of success or progress of implementation of risk reduction strategies have to be determined by product contamination levels. The trends in campylobacteriosis in the individual Australian jurisdictions varies and this would have to be taken into account in choosing aggregated Australian data or data from another individual state or territory as a proxy measure of illness (Figure 18).

In Australia, campylobacteriosis is the most common bacterial foodborne illness, estimated to cause 179,000 cases/yr. (108,500–290,000, 90% CrI), 3,200 (2,100-4,500, 90% CrI) hospitalisations and 3 (2-14, 90% CI) deaths. In 2015, the national notification rate of campylobacteriosis was 131.9 notifications/100,000 population and circa 2010 the food attributable proportion was 77%.

Lack of surveillance of campylobacteriosis in NSW is a constraint in developing evidence- and risk-based food safety management approaches.

Food Attribution

In a case-control study conducted by OzFoodNet in 2001-2002, consumption of undercooked chicken and offal were risk factors for *Campylobacter* illness along with ownership of domestic chicks and puppies (Stafford et al., 2007). It was reported eating chicken either cooked or uncooked, and poor handling of or cross-contamination by chicken during food preparation may account for approximately 30% of cases in Australia each year. An estimated 3,500 cases were attributed to eating offal such as

livers. Eating chicken was not identified as a risk factor in children \leq 5yr. although animal contact may contribute.

Outbreak data is limited due to the sporadic nature of the illness reports. Based on data from 33 *Campylobacter* outbreaks in Australia, 2002-2006, 27 (82%) were foodborne or suspected foodborne, 3 (9%) waterborne, one person-to person, and 2 of unknown transmission routes (Stafford, 2013). Poultry (chicken or duck) was linked with 11 of 16 (41%) outbreaks where a food was identified, unpasteurised milk and salads were associated with 2 outbreaks. Undercooking products (44%) and cross-contamination (25%) were main contributing factors. Dishes based on poultry livers have caused an increasing number of outbreaks. In NSW between 2011 and 2014 there were 3 campylobacteriosis outbreaks attributed to duck liver parfait, chicken liver pate on toast and one unknown (OzFoodNet Annual Reports NSW cited 24/04/16 at <http://www.health.nsw.gov.au/Infectious/foodborne/Pages/ozfoodnet-rpt.aspx>).

Risk management and regulatory approaches

Campylobacter would be considered a hazard to be controlled in HACCP plans of various Food Code commodity-based standards. From limited outbreak data and case-control studies, chicken is an important food vehicle. Milk has been implicated when served unpasteurised outside the regulatory system controls and salads that may have been cross-contaminated during handling have been implicated. Poultry meat is reviewed here.

Meat and poultry

PPPSs for meat and poultry and the Meat Food Safety Scheme are described under meat and poultry regulations and NTS above and the baseline prevalence and concentration of *Campylobacter* in NSW in 2008 are shown in Table 13. The Food Code safety standards apply at retail and food service and address the need for thorough cooking of chicken and prevention of cross-contamination between raw poultry and cooked poultry and other RTE foods.

FSANZ undertook a quantitative risk assessment of poultry meat production and estimated the impact of various interventions on health impacts in Australia (FSANZ, 2005). It was estimated lowering *Campylobacter* prevalence at the end of processing by 50% and 75% would lower health risk by 53% and 78%, respectively, and lowering levels on carcasses by x5 and x10 would lower risk even more by 84% and 93% respectively. Other interventions such as reducing cross-contamination (by 50% and 75%) and under-cooking (by 50% and 100%) were estimated to result in more modest reductions of 27-35% and 19-43%, respectively.

In the PPPS 4.2.2 for Poultry Meat the following are required:

- Primary production: documented hazard-based food safety plan; traceability of recipient of stock;
- Processing NRTE poultry meat: documented hazard-based food safety plan; food safety skills and knowledge training of workers appropriate for their tasks, traceability to supplier and recipient;
- Processing RTE poultry meat: standard 4.2.3 applies.

A requirement for biosecurity measures is not included in the PPPS 4.2.2 and it was intended the poultry industry voluntarily adopt guidelines provided by other government departments and industry groups.

While the FSANZ risk assessment identified points for interventions with significant impact on risk, the PPPS is general requiring industry to determine hazards and demonstrate they are controlled. There have been no health goals or food safety objectives established for *Campylobacter* in poultry meat in

the past although it is understood microbiological criteria and process criteria for process verification are being considered currently (NSW FA pers. comm.) It is not clear that these are being related to health risk reduction outcomes and, if they are not, then it will be difficult to relate them to expected levels of health protection.

In the NSW Poultry Verification Program carcasses at processing plants and pre-packaged and bulk chicken, skin on and off, at retail are randomly tested for APC and faecal indicators, and qualitatively and quantitatively for NTS and *Campylobacter*. Acceptable levels of *Campylobacter* are set at $\leq 10,000$ cfu/carcass although there are no mandatory limits or sampling plans (NSW FA pers. comm.). Offal such as chicken livers is not included in verification testing.

Consumer education and information programs are provided by the NSW FA and focus on thorough cooking of poultry meat and prevention of cross-contamination during food handling. The epidemiological evidence indicates the young, young adults and older adults are groups at greatest risk.

Evidence for success

Campylobacteriosis incidence and outbreaks

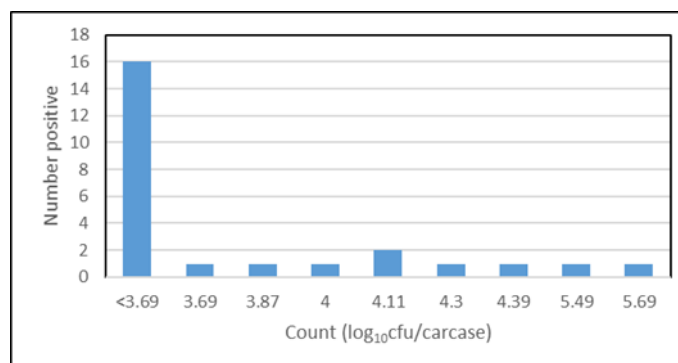
It is not possible to comment on the success in reduction of human illness for the reasons described above e.g. no case surveillance data and limited outbreak data as most cases appear sporadic. Between 2011 to 2014, 3 campylobacteriosis outbreaks were recorded and undercooked chicken livers were implicated in 2 (OzFoodNet Annual Reports, cited 24/04/16 at <http://www.health.nsw.gov.au/Infectious/foodborne/Pages/ozfoodnet-rpt.aspx>).

Food contamination

In the Food Regulation 2010, unpasteurised goats milk was the only product for which *Campylobacter* testing was required and from 2009-2014 and no positives were reported. The Poultry Verification Program began in 2015.

Poultry. The results of earlier poultry process verification monitoring between 2014-2015 are shown in Figure 22 and from 2015 to April 2016 in Figure 23. Comparison of these data and the baseline should be interpreted cautiously as the sample sizes were different. *Campylobacter* detection rates, similar to NTS, trended down in 2014-2015 compared with the baseline; however, the concentration levels remained similar. *Campylobacter* results in 2015-2016 are not much different to the baselines. In 2015 to April 2016, about 83% chicken portions were positive and most were <10 cfu/cm². All carcass samples were positive and about a third of these were $\geq 4 \log_{10}$ cfu/carcass, the level considered acceptable (Figure 24).

Figure 24 Counts of *Campylobacter* on positive chicken carcasses in the Poultry Verification Program 2015 to April 2016 (Data from NSW FA pers. comm.)



Campylobacter prevalence has been trending down compared with the 2008 baseline compared with concentrations on carcasses that are not much changed and present greater risk.

Gaps and opportunities

As for salmonellosis, hazard/hygiene and commodity based risk reduction measures alone have not been sufficient to reduce the health risk of campylobacteriosis to desired levels of protection in the countries reviewed. Therefore, specific pathogen-product approaches have been developed. Consumption of poultry meat has been a common, important risk factor in foodborne campylobacteriosis in all the countries reviewed to varying degrees. Data on the illness in NSW is lacking, most cases if reported would likely appear sporadically and there are few outbreaks to provide evidence. In Australia, 77% cases are estimated to be foodborne and about 30% of these estimated to be transmitted by chicken meat consumption. Limited foodborne outbreak data in NSW implicates chicken meat as a source. A comprehensive control program requires a sound understanding of the illness and transmission pathways as available evidence indicates reduction in chicken contamination will impact only on a proportion of campylobacteriosis cases.

A gap exists in the lack of evidence of campylobacteriosis incidence, food source and reservoir attribution in NSW. The opportunity to enhance control measures to lower campylobacteriosis incidence will depend on the quality of the evidence base.

Poultry meat. The NSW FA has introduced performance monitoring programs although the limits are not related to health outcomes, linked with statistical sampling plans and are not mandated. The major developments with approaches in the USA, NZ and the UK that differ from the NSW FA approach have been the establishment of health goals for the reduction of the disease and the articulation of these into food safety objectives for specifically attributed foods such as poultry. In the USA and NZ these have been mandated as quantitative performance targets that guide industry and regulatory verification programs. NZ claims the introduction of mandatory performance targets was the single most important factor in their success in reducing campylobacteriosis transmitted via poultry meat (Lee et al., 2015). This data has been used to guide industry managers, modify, revise and adapt strategies depending on progress in reducing illness.

The countries have expressed their PSs in different ways e.g. reducing the high contamination levels and/or prevalence levels in chicken at the end of processing. These are not simply set as limits but also defined in terms of the level of stringency in the sampling plans required. The programs have been underpinned by sound epidemiological surveillance and investigation, and food attribution, understanding transmission pathways and risk factors. The EU Regulation has not considered *Campylobacter* as a food safety criterion due to its expected presence in poultry although anecdotal evidence suggests it is considering the UK FSA targets of <90% of carcasses carrying <1,000 cfu/g and no meat should carry more than 10,000 cfu/g.

It is notable that the UK industry has had to achieve their performance targets without the use of antimicrobial decontamination as a processing intervention in contrast to the other countries. On farm factors are also considered important with enhanced biosecurity, controlling depopulation and transport hygiene. Flocks are tested prior to slaughter and this information is provided to processing HACCP managers to make adjustments in their processing to reduce contamination risk if required.

Behavioural aspects of all food chain actors have been recognised in each country, particularly the UK and NZ. Making process performance or the categorisation of establishments based on performance more broadly available in the public domain is an approach of the UK and the USA to incentivise improved performance; the need to have a whole of chain commitment from leaders and managers down was identified in the UK and NZ, and, the need for campaigns on safe food handling for consumers and food services was recognised by all.

A gap exists in setting a quantifiable expectation of industry performance in the reduction of *Campylobacter* in poultry by the end of processing. There is an opportunity to require poultry processors to verify their processing performance and meet quantified performance targets measured using appropriately stringent sampling plans and to share information.

Listeria

Evidence of public health and economic burden

The Australian *Listeria* Management and Surveillance System together with genotyping of isolates was established to improve detection of clusters of illness and to prompt timely public health action. In 2014 in NSW there were 23 notifications of listeriosis, 2 perinatal, slightly lower than the previous 5 yr. average of 28.4 cases (Ward et al., 2014). The majority of cases were >60 yr. and had immunosuppressive conditions and 5 (22%) cases aged 46, 69, 82, and 85 yr. died. There were 2 perinatal cases, one miscarried at 12 weeks and the other survived.

Outbreaks/clusters have been periodically reported e.g. in 2014, there were 3 clustered notifications, in 2013, 3 cases and 1 death, and in 2012, 39 cases were reported in a multijurisdictional outbreak.

Food attribution

In a case-control study of Australian patients between 2001 and 2004, the main risk factor for perinatal listeriosis was living in a household where a language other than English was spoken (Dalton et al., 2011), an observation also made in the UK. For non-perinatal cases risk factors identified were prior hospitalisation, use of gastric acid inhibitors, and consumption of camembert. Forty percent of prior hospitalised patients were exposed to high risk foods during hospitalisation. The evidence from outbreaks in NSW is similar, where in 2012 to 2014 clusters were linked with commercially prepared profiteroles in a hospital setting, soft cheese made by a Victorian producer, and consumption of sandwiches served at a private chemotherapy clinic.

Risk management and regulatory approaches

L. monocytogenes is a hazard to be controlled in food safety plans for RTE foods under the various Food Safety Schemes and the Food Standards Code, with specific standards for control in RTE meat and poultry products and foods for vulnerable persons. Microbiological criteria are in place for high risk RTE foods categorised based on potential for *L. monocytogenes* growth based on intrinsic properties of the food of pH and water activity e.g. <100 cfu/g if no growth and not detected in 25g if growth will occur during shelf life.

The Food Safety Schemes Manual provides enforcement of these standards with requirements for product testing for *L. monocytogenes* and environmental and work surface testing for *Listeria* spp. with sampling plans for RTE meat and poultry products at processing and retail, and product testing of dairy products, fresh cut fruits and vegetables and cooked/smoked seafood (NSWFA, 2015). While the Food Regulation 2015 (NSWGov, 2015a) states food analysis is required by licenced vulnerable person's food businesses, according to the Manual (Nov 2015), no routine analysis of food or water is currently required by the NSW FA for such licensed businesses.

Periodic surveys have been conducted of high risk foods to support regulatory activity (NSW FA cited 09.05.16 <http://foodauthority.nsw.gov.au/aboutus/science/market-analysis/ready-to-eat-meats>). In the 2008 survey of RTE meat products 6 of 154 (4%) samples had low levels (≤ 10 cfu/g) of *L. monocytogenes* (2 ham, 2 salamis, 1 silverside, 1 roast beef). In 2011-2012, 303 sliced/diced pre-packaged RTE meats and poultry were sampled from supermarkets, green grocers and delicatessens across Sydney. Two samples (ham and silverside) that could support growth of *L. monocytogenes* were

contaminated with 10 cfu/g. Among 280 RTE chilled foods tested between 10/15 and 06/16, *Listeria* was detected in 9 (3%) of which 4 (1.4%) were confirmed *L. monocytogenes*, with counts of 20 cfu/g for one and the others <10 cfu/g (NSW FA pers. comm.). The *Listeria* positive samples included sandwich (3), wrap (2), sushi (1), hot dog (1) and salad (2) type products.

A baseline study of 91 hospital and care facilities was conducted in 2003 before implementation of the national standard for food served to vulnerable persons (NSWFA, 2004). Ninety-two percent of businesses served at least one type of high risk food. The most common high risk foods served were delicatessen meats (86%), lettuce (57%), rockmelon (55%), soft cheese (47%) and sprouted seeds (9%). In the microbiological analysis of 341 foods in the same survey, *L. monocytogenes* was detected in salads and sandwiches in 6 businesses, 7% of RTE samples overall. Delicatessen meats were a common ingredient in the contaminated complex foods.

In the Microbiological and Verification Testing Program of foods manufactured in NSW under the Regulation, from 2009-2014, 1,271 RTE food products were tested, 96% complied overall (NSWFA, 2014b). *L. monocytogenes* was detected in one of 236 cheese samples, 5 of 471 RTE meat, poultry and pate samples and 2 smoked fish samples. No detections were reported for 37 fresh cuts and 50 sprout samples. A breakdown in manufacturing processes was observed where non-compliance was reported. In 2014-2015, *L. monocytogenes* was not detected in 194 samples analysed (NSWFA, 2016).

Consumer education and information

Extensive information on the risk of listeriosis for vulnerable groups and on risk management of *Listeria* in food manufacture and service is available from the NSW FA, Australian government agencies and other sources. In the 2003 baseline survey the NSW FA had identified at the time there was a need to provide industry with clear guidelines and a model food safety plan.

Evidence for success

Campylobacteriosis incidence and outbreaks

The incidence of listeriosis is low and can appear greatly inflated by the occurrence of an outbreak, particularly if it involves more than a small cluster of cases (Figure 19). The rate of occurrence of cases and outbreaks has been fairly steady since 1997. Of greatest concern is the severity of the illness in vulnerable groups as seen with 5 deaths in 2014 (Ward et al., 2014).

Food contamination

The contamination rate of *Listeria* in high risk foods that have been a particular focus of regulations and industry guidelines, such as dairy, RTE meats and poultry, and seafood, is low and has improved over time. Where non-compliance was reported in food manufacture poor applications of process controls were identified. In 2003, the rate of detection of *L. monocytogenes* in prepared food for vulnerable persons was higher and those foods commonly including delicatessen meats; however, this was before implementation of the Standard for this food group and may have been caused by post-manufacture mis-handling.

Gaps and opportunities

The experience of listeriosis in NSW has similarities to the other countries reviewed. The disease severity is a major concern although the incidence is low and can vary in response to the emergence of exposure factors and/or changes in vulnerable populations. Other countries have set health goals for lowering the incidence of listeriosis; however, they have taken into consideration increased exposure due to the popularity and widening variety of convenience chilled RTE foods available in the marketplace, and increases in population groups such as immunosuppressed and older adults living in and out of the community, and in low income and ethnic minority groups. From NSW outbreak data,

food for institutionalised vulnerable persons remains an issue. The use of genomic typing may assist in identification of clusters among case notifications in the general community and attribution of foods. There is a gap in the NSW FA program as there are no specific health goals for listeriosis established within the overall foodborne illness reduction strategy and detailed identification of the priority consumer groups beyond “vulnerable”. There is an opportunity through genomic typing and case investigation to provide new insights into transmission pathways and risk factors.

A gap exists within the Food Safety Strategy for a health target for listeriosis. There is an opportunity through the *Listeria* Management and Surveillance Program to identify sub-groups of vulnerable persons in the community and improved food source attribution for development of targeted control measures.

In the countries reviewed as well as NSW, the high end food retailers and manufacturers have generally implemented successful control programs in response to listeriosis crises and subsequent regulations, and the presence of *Listeria* in products has decreased to low levels at the point of manufacture. Internationally, this has shifted the focus of control measures to improvement of compliance among the small and medium size manufacturers and to assisting improvement in post-manufacture handling by smaller retailers, and food service and catering sectors, that have been shown to have higher non-compliance with regulations and to be key sources of foods for the identified vulnerable groups. This has included smaller retailers, markets and informal/illegal food suppliers for low income and ethnic groups and providers of food for older adults and immune-compromised persons resident in the community as well as those institutionalised.

Internationally, there is a trend in strategies for *Listeria* control in food manufacturing and retailing to re-focus on working with small to medium enterprises and businesses supplying identified vulnerable groups and those that have poor compliance histories, to improve their performance.

In the USA, further focus has been applied in the food handling sector to improve *Listeria* control with changes to the requirements in the Food Code 2013. For example, specific hygiene measures are required taking into account the ability of the bacterium to form biofilms e.g. food processing equipment should be disassembled every 4 hours and scrubbed, and sanitisers rotated to prevent development of *Listeria* resistance.

Additional guidance could be considered for control of *Listeria* in the post-manufacturing sectors with the same rigor as has been required in the manufacturing sector.

Other countries have observed changes in patterns of priority food sources with the progressive success of existing control measures and these warrant considerations. In the USA, food attribution studies have identified fresh produce, including those mass produced and widely distributed, has emerged as an important food vehicle and is seeking new and improved regulatory controls. Dairy foods made from raw milk continue to present a risk where allowed for consumption. The USA is exploring additional measures for control of these products with industry. NZ has established process criteria for storage temperature and time limits to consumption for raw milk in addition to hygiene and mandatory labels that must state the pasteurisation status of the milk and the health risks. Conducting sampling/inspection programs based on risk are considered more effective investments in food safety.

Changes have been made in testing requirements in high risk foods. In the UK there is a microbiological criterion for the category of RTE foods for infants and for special medical purposes that is more stringent than that for other RTE foods (not detected in 10/10 25g samples). In the USA the FSMA has recently broadened the requirement for process verification testing, recommending monitoring for *Listeria* spp. in end products and the processing environment for certain RTE dairy products, e.g., facilities making soft cheeses exposed to the environment as applies in RTE meat and poultry products.

Education and information for consumers and industry is recognised as an important part of control strategies in all countries. The UK has used studies of knowledge, attitudes and behaviours to understand factors resulting in poor practice and compliance and those that limit uptake of education and information material. Understanding the vulnerable groups and their food procurement, consumption and handling has been used to develop more effective messages and the most effective channels for delivery of the messages. Date labelling is required in other countries in various forms. In the UK, it was found use-by dates relevant for *Listeria* control may not be as effective as desired among vulnerable persons such as older adults and low income groups for a variety of reasons. In depth evaluation of the effectiveness of this regulation could be explored from a consumer behavioural perspective.

There is no specific requirement for process verification in food businesses for vulnerable persons in the Food Safety Schemes Manual. An opportunity exists to consider a requirement for process verification using appropriately stringent food safety and hygiene criteria for high risk foods prepared for highly vulnerable groups. Inspection and verification programs are most effectively based on risk and compliance history.

In the UK, investigation of the understanding by small businesses and enforcement officers of the application of food safety criteria that define the limits of *L. monocytogenes* in RTE foods based on intrinsic properties of food and shelf life found this aspect of regulation was poorly understood impacting on process control and inspection outcomes. This information was used to modify and improve industry guidance materials and training of enforcement officers.

An opportunity exists to investigate the social and behavioural factors that influence consumer and industry uptake of education and information provided by authorities, application of microbiological criteria, and use of date labelling on products, to improve their effectiveness. The level of understanding of food safety criteria for *Listeria* in RTE foods among auditors and compliance officers should be appropriate for their role.

Technologies and other intervention measures

Technologies and other intervention measures that reduce the prevalence and concentration of pathogens can be used at points along the food chain to contribute to risk reduction. Control strategies are best applied through the food chain and frequently the greatest risk reduction is achieved when multiple hazard and hygiene controls are applied. The use of an effective pathogen reduction step at one point in the food chain though is not an excuse for poor practice at others. The use and choice of intervention methods varies between countries depending on their food regulations and consumer acceptance. For example, in the EU the use of chemicals in decontamination of food is limited and Class A shell eggs have to be kept dry, therefore on farm, food formulation and non-chemical intervention methods are sought. In the USA, irradiation of food has been approved as an effective

pathogen control for some foods, yet its use has been limited by lack of consumer acceptance while chemical and other means for pathogen reduction are accepted.

Some technologies and intervention approaches are described for NTS, *Campylobacter* and *L. monocytogenes* in the foods most commonly attributed in their transmission. It is noted this is not intended to be a comprehensive review of this topic. There is a focus on interventions supported by the regulatory authorities in the countries reviewed. Information on industry uptake of some of the approaches and their success is difficult to obtain via an electronic review process and some processes are patented.

The more recent Codex guidelines for control of NTS and *Campylobacter* in chicken, and NTS in beef and pork referred to in the section on the CAC identify hazard-based controls though chain and indicate the expected level of pathogen reduction for each. These controls have been identified and reductions quantified following extensive literature review and international expert consultations conducted by the FAO/WHO and provide an extensive guide on expected outcomes of control measures. Earlier guidelines do not have this information included although reviews were also conducted and those for poultry, eggs, fresh produce and low moisture foods can be found via the FAO Food Safety and quality website index <http://www.fao.org/food/food-safety-quality/a-z-index/en/> (cited 18/05/16) and the draft report for NTS control in beef and pork can be accessed at <http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-712-47%252FSalmonella%2Bexpert%2Bmeeting%2Breport%2B-%2BOct%2B20%2B%25282%2529.pdf>.

Evaluation of intervention methods has become more rigorous with studies scrutinised using systematic reviews, methods assessed for credibility, use of inoculated samples and whether evaluated in situ. As a result, some scientific reports are considered along with confidence ratings of the results. This is reflected in the recent systematic review of NTS in beef and pork conducted by FAO/WHO to advise development of CCFH Guidelines where effective interventions were found to be limited (Young et al., 2016). This process was not used here.

Bacteriophages

There has been renewed interest in the use of bacteriophages as a control measure for NTS, *Campylobacter* and *L. monocytogenes* in place of chemicals and antimicrobials (Sillankorva et al., 2012). They have proven effective in some live production animals and following direct application on a range of raw and processed foods, food contact surfaces, equipment and in the processing environment. Commercial phage preparations have been used pre-harvest in various ways such as direct application on live animal hides to reduce the level of NTS or addition to feed to reduce NTS in poultry. *Campylobacter* phages have been used experimentally to reduce pathogen levels in chickens although the bacterium's genomic instability and potential for resistance may cause challenges in field use. Post-harvest application for NTS control have been applied to meat, RTE foods and fresh produce. *L. monocytogenes* phages have been commercialised for use in food products and food processing facilities. The applications have to be considered on a case by case basis as there are multiple factors such as the food matrix, intrinsic and extrinsic factors that influence applications.

Lake et al (2013) included bacteriophage treatment of broilers by adding phage to water or feed in a cost-effect analysis of interventions for *Campylobacter* in poultry in NZ (Lake et al., 2013). The ingested phage would reduce faecal contamination and lead to a reduction in environmental and carcass contamination and, should a product become commercially available, it was estimated to be a low cost and effective intervention to lower levels of illness from consumption of chicken meat.

The USA FSIS includes bacteriophages as safe and suitable for use in production of meat, poultry and egg products (FSIS, 2016a). NTS and STEC O157 targeted phages are approved for use on live cattle hides and feathers of live poultry pre-slaughter, RTE poultry products prior to slicing and on raw poultry carcasses and parts. *L. monocytogenes* targeted phage is approved for RTE meat and poultry products and as unspecified phage preparations for RTE meat and poultry and red meat parts and trim prior to grinding. Bacteriophages were not considered a recommended control measure of cattle hides in the FAO/WHO review (FAO/WHO, 2015).

Chemical decontamination

Approaches to chemical decontamination of raw foods vary between countries from the EU where its use is very restricted to the USA where use of an antimicrobial wash is mandated in beef processing. There is a myriad of scientific publications of traditional and new disinfecting and sanitising agents for use in the food industry, and a review is beyond the scope of this report. USA companies and researcher are particularly active in this area given their regulations, support and encouragement from government agencies (FSIS, 2016a). Most decontamination methods of this type produce about 1-2 log₁₀ reductions in pathogens (See Codex and FAO/WHO expert consultations referred to above). In the past chlorine based sanitisers have been most common and neutralisers used to prevent any sanitiser carried over into product samples and rinses from inhibiting recovery of the target pathogens in process verification testing. There has been some debate in the USA on new sanitiser products with different formulations and whether they are adequately neutralised during microbiological analyses (Gamble et al., 2016).

Processing technologies

There are a variety of thermal, non-thermal and combination food processing technologies that can be applied to ingredients and finished products to reduce pathogens. Examples of non-thermal technologies are high pressure processing, microwaves, high-intensity pulsed electric fields and UV light. These processes produce consistent pathogen reductions equivalent to traditional processing (e.g. pasteurisation) while producing a higher quality product with an extended shelf life. While the non-thermal technologies have been promising the uptake by industry has been slow. In EU member countries where alternatives to use of chemicals are required these technologies offer an alternative option and there is renewed interest. A program referred to as HIPSTER (DEPLOYMENT OF HIGH PRESSURE AND TEMPERATURE FOOD PROCESSING FOR SUSTAINABLE, SAFE AND NUTRITIOUS FOOD WITH FRESH-LIKE QUALITY) that will run for 30 months to August 2017, has been established to promote high hydrostatic pressure plus temperature processing (Cited 17/05/16 at <http://hipster-project.eu/>). Nine EU countries will work together to develop and demonstrate fit for use knowledge, tools and industry equipment, to help achieve greater implementation of this technology.

The UK FSA has supported the use of steam and ultrasound (SonoSteam) evaluated by a UK chicken processor who has taken up the technology as a major investment. The process uses a combination of steam and ultrasound to inactivate *Campylobacter* on the skin and internal cavities of chicken (Cited 17/05/16 at <http://sonosteam.com/technology/>). The product manufacturer claims bacteria on the surface and in microstructures and pores of chicken skin are inactivated. It was shown in practice to reduce *Campylobacter* on neck and breast skin by 80%.

Shell egg decontamination

Shell eggs present a unique challenge for decontamination due to the nature of the product. Microbial decontamination procedures such as washing and use of disinfectants and sanitisers have been applied for decontamination of shell eggs for decades in those countries where it is allowed. In the USA, egg production has to meet the equivalent of a pasteurisation process and a 5 log₁₀ reduction in

NTS is considered efficient for pasteurisation. The validated approach used has to be approved by the FDA (FDA, 2013c). Much interest in this area comes from the USA due to regulations. Novel disinfectants and sanitisers, decontamination technologies and combinations thereof have been reported experimentally; however, they vary in their ability to achieve an equivalent performance to a 5 log₁₀ reduction in NTS and in their effects on the egg shell structure and functionality of the contents (See Galiş et al., 2013 for review).

Whiley and Ross (2015) in Australia reviewed approaches to control of NTS in eggs from farm to plate (Whiley and Ross, 2015). They concluded for shell egg decontamination, irradiation and pasteurisation were the only methods certain to reduce NTS. However, they report that the latter treatments can result in changes to the egg's sensory and functional properties making them less suited for general consumption although a possibility for high risk vulnerable populations. The Australian Egg Corporation Ltd provides a Code of Practice for their industry that includes general shell egg washing (Cited 17/05/16 at <https://www.aecl.org/assets/Uploads/Resources/Code-of-Practice-for-Shell-egg-production-grading-packing-and-distribution-2009.pdf>).

Irradiation may be suitable for inactivation of NTS on the egg shell and in the internal content. The level of NTS reduction increases with the dose applied; however, the effects on the functional properties of the egg contents can also increase with increasing dose. Low dose irradiation can still cause changes in egg white although these can be beneficial effects for some types of egg processing end use (The Poultry site 21 March. 2014. Cited 17/05/16 at <http://www.thepoultrysite.com/articles/3105/irradiation-of-shell-egg-on-the-physicochemical-and-functional-properties-of-liquid-egg-white/>).

FDA has approved the use of ionizing radiation for shell eggs (FDA, 2013c). Shell eggs that have been treated with an approved ionizing radiation process are not considered equivalent to pasteurised eggs because shell egg pasteurisation has to achieve a 5 log₁₀ kill process for SE, while the approved ionizing radiation process may achieve only 2 or 3 log₁₀ reduction. Therefore, eggs treated by an ionizing radiation process alone must be held under refrigeration, as it cannot be guaranteed that SE will be eliminated in all treated eggs. Irradiated eggs must be labelled as such.

There are patented processes and equipment available commercially in the USA for in shell egg thermal pasteurisation. Eggs may be heated to an internal temperature around 55-56°C that can be achieved using hot air over a long time period or more efficiently using shorter water bath heating without effecting quality, followed by sealing with food grade wax to prevent further contamination, and refrigerated storage (Davidson's Safest Choice <http://www.safeeggs.com/safest-choice-pasteurized-eggs/how-we-pasteurize-eggs>).

Other non-thermal pasteurisation technologies have been investigated and some have achieved at least a 5 log₁₀ reduction of NTS with no or little functional effects on the egg shell structure and contents. Examples are pulsed light and ultrasound/thermal treatments that have been used experimentally for surface decontamination of shell eggs (Galiş et al., 2013; Lasagabaster et al., 2011). The USDA has applied to patent with research collaborators a pasteurisation process using radio frequency (Princeton University Research News. Cited 17/05/16 at <http://www.princeton.edu/research/news/features/a/?id=10909>). Other approaches such as using atmospheric cold plasma or microwave technology may achieve lower reductions and would have to be combined with other controls (Galiş et al., 2013).

Summary

There were common threads in the current approaches to control of NTS, *Campylobacter* and *L. monocytogenes* foodborne infections in the three countries reviewed, the USA, the USA and NZ. There was also a parallel with the progressive approach of the CCFH on food safety risk management and guidelines related to these pathogens and this was not surprising as these countries play an active role in guiding and developing the work of the CCFH. Australia also contributed to the works of the CCFH and has adopted some of the CCFH approaches although not all to the same extent.

Pathogen reduction strategies

Hazard control programs supported by basic sanitation and hygiene procedures have progressively been applied to the whole food chain and provide the foundation for food safety management in all the countries reviewed. While this approach has been successful in bringing some microbial foodborne illnesses under control it has been less successful for control of certain foodborne zoonoses and listeriosis to acceptable levels. Commodity specific strategies addressing a range of hazards were developed and these have had varying levels of success. Subsequently more targeted pathogen specific strategies for prioritised foods have been developed. At the same time, developments in risk analysis and risk management have resulted in their risk managers moving to a risk- and evidence-based approach using quantitative tools to target risk management options that would have the greatest impact on reducing risks at points along the whole food chain continuum. This has been further enabled by improved pathogen analysis and typing, the development of food safety metrics, and data from enhanced epidemiological surveillance and food attribution studies. The countries have a common approach with governments setting national goals for the respective foodborne illnesses and their agencies responding by developing pathogen/food specific strategies to meet the goals. The agencies follow a systematic process or a risk management framework with preliminary activities prioritising food groups by risk, estimating their contribution to the health goals and selecting effective risk reduction measures, followed by implementation, monitoring and review. The expectation of performance from risk reduction measures at points along the chain are articulated as performance targets that have to be met by food chain participants to collectively achieve the health goals.

This general approach appears to have been the most important regulatory process in driving success as opposed to the beneficial effects of individual interventions. For example, NZ claims this has been the most important measure in their success in controlling campylobacteriosis resulting from chicken meat consumption and the UK has a similar approach, it has impacted on NTS control in eggs and chicken in the EU, in the USA it drives the control of *Listeria* in RTE foods and pathogens in fresh meat and poultry and is the basis of new regulations. Within these systems food chain participants are mainly able to choose the interventions for their establishment; however, they have an end point driver in that their performance has to meet the defined targets. The performance targets are guides for industry and used in regulatory measures of process verification and compliance, in identifying need for modification of direction, and in measuring success.

Meeting the performance targets has been a result of a combination of intervention measures applied through chain, some following regulatory guidelines and some voluntary, and some industry initiated. Pathogen targeted approaches have been successful, however, these rely also on continuing improvement of general food safety- and hygiene-based measures. The levels and the speeds of achieving success are influenced by various and differing external drivers such as the nature of the and complexity of the food supply and the local culture, commitment of the government and food chain participants, cost, and political and consumer constraints.

While all of the bacterial pathogens reviewed are among those of key concern for the countries reviewed, there are competing priorities e.g. foodborne viral infections and STEC, and the priority ranking among these bacterial foodborne infections differs. Campylobacteriosis is a priority concern in the UK and NZ while in the USA it has been of lesser importance. Vally et al (2009) reported that in 2001 the rate of campylobacteriosis in Australia was 12 times that in the USA after accounting for different reporting systems (Vally et al., 2009). Salmonellosis is the most important of the 3 illnesses in the USA and both the UK and the USA have experienced epidemics of SE infections. Listeriosis is important in all countries due to the severity and high mortality. The food groups of most importance vary with the local setting, food supply and social culture although some are common e.g. NTS and egg and egg based dishes, *Campylobacter* and chicken meat and *L. monocytogenes* in chilled RTE foods supporting its growth. The priority of foods of concern are dynamic, some foods come under control giving others prominence, and some new foods or foods from changing production/processing systems or preference have emerged. In the USA *Campylobacter* is more important in dairy products than chicken meat though in specific exposed community groups, NTS and *L. monocytogenes* have emerged as more important pathogens in fresh produce than meat and dairy foods, respectively. Red meat is only of concern with particular products e.g. minced or non-intact cuts, while pork is of increasing concern in the EU and USA. The range of interventions permitted influence the choice of risk management options that has had some influence on the rate of progress.

Salmonellosis

Meeting health targets for salmonellosis appeared the most challenging due to the diversity and ongoing changes of foodborne transmission pathways, the multitude of risk factors and dynamics among NTS types that are a moving target. Strategies for control of foodborne salmonellosis in the USA and UK are strongly influenced by their earlier SE epidemics and therefore the specific characteristics of that serotype and the main food vehicle, eggs; however, as the SE epidemics have waned other NTS types and other attributed foods have emerged. The USA has identified a wide range of food pathways to be addressed, while NZ's strategy is broad due to lack of attribution data and they are investing in filling this knowledge gap.

In the UK and USA SE epidemics, poultry are the reservoir host; eggs are the main vehicle with chicken meat to a much lesser extent. CCFH and both countries undertook quantitative risk assessments and scientific studies to guide a risk-based choice of interventions with quantifiable outcomes. Both countries focus on farm prevention of shell egg contamination and post-harvest SE growth in eggs by refrigeration, pasteurisation of egg products, and food handler/consumer education. Also common, is the setting of quantitative performance measures for incoming stock, layer flocks during production, and shell eggs, and process criterion for egg product pasteurisation with corrective actions to prevent contaminated eggs and products entering the marketplace. Differences in approaches occur reflecting their regulatory limitations on intervention measures. In the UK/EU control measures for shell eggs begin at the top of the poultry production pyramid, mandatory maximum national flock prevalence levels are set at a maximum of 1%, on farm controls are required including voluntary vaccination (mandated in Some EU Regs. and UK farm assurance schemes), testing programs for SE in flocks at different production stages and shell eggs and slaughter of positive breeding flocks and prevention of eggs from positive layer flocks being placed on the market are mandated. The USA require treatment of eggs to be equivalent to a pasteurisation process resulting in at least a 5 log₁₀ reduction in SE either through on farm measures and testing programs, pasteurisation or an equivalent. On farm measures are similar, vaccination and feed treatment is recommended, and a systematic flow of testing is required from environment to flocks to eggs with diversion of flocks or shell eggs at each level if positive. The EU requires Class A shell eggs to be kept dry while in the USA they can be washed with

chemical decontamination agents and both countries require temperature and time control of eggs post-harvest. Shell eggs are stamped and the USA requires labelling of shell eggs at retail with safe handling instructions. These measures are complimented with specific requirements in the Food Codes covering food service, with recommendations for use of pasteurised products in catering and restaurants and in foods for vulnerable persons, and with extensive information and education for consumers on the risks of consumption of raw or undercooked eggs. Both countries have had success in the reduction of SE in eggs although this has been greater in the UK. The UK FSA has recently relaxed some advice for pregnant women not to eat raw eggs/egg dishes. The UK gives particular credit to the use of vaccines in their success and farm quality assurance schemes. In the USA, SE has rebounded in the 2000s with chicken meat becoming an important food source and an increase in SE has been observed in young broilers.

As SE in poultry has come under control other serotypes have assumed a higher proportion among human and non-human NTS isolates. In the UK the overall NTS prevalence has increased in poultry breeders and layer flocks. The EU regulations for foodborne zoonoses have been redefined to reflect health risk and now specify "regulated" NTS serotypes which are those most common in human salmonellosis e.g. SE and Typhimurium (and variants) for layer flocks and broilers with the addition of Virchow, Hadar and Infantis for breeders. Sweden has had a more extreme strategy for elimination of all NTS types in meat, poultry and eggs beginning at the farm level with mandatory slaughter of positive flocks, testing of lymph nodes in cattle and pigs, testing of carcasses and equipment in slaughter houses and diversion of positive lots. While Sweden claims to be virtually NTS free, the program is considered to require modernisation and is a high national cost so modification of the approach setting defined targets along the food chain is being considered.

Bacterial pathogens in red meat have been under control for some time and STEC have become equal or more important than NTS. The USA mandates the use of at least one validated decontamination treatment during slaughter and the EU has allowed use of lactic acid sprays on beef carcasses. The USA use NTS testing of carcasses as a process criterion and in the EU additional NTS food safety criteria are applied for NTS in meat to be eaten raw or minced meat or preparations that might be undercooked. Concerns have arisen with specific products and consumer practices e.g. raw or undercooked products, and minced meat and non-intact meat cuts. Labelling with warnings and safe cooking instructions are required on these latter products. Control of NTS in minced beef, the role of lymph nodes and control measures, are under investigation in the USA. Increased control of NTS in pork is under investigation in the EU and USA and recently CCFH have produced draft guidelines. In the UK, attribution of pork in salmonellosis has increased. This may be due to comparative changes with the control of NTS in eggs and poultry as the prevalence in herds and processing is unchanged. The USA is surveying pork production and PSs may follow.

The approaches to control of NTS in chicken meat are not dissimilar to that for eggs with an on farm focus in the UK and multi-hurdles on farm and during processing in the USA. The EU has requirements for not more than 2% broiler flock prevalence and uses regulated serotypes (Enteritidis and Typhimurium) as targets. Broiler flock testing was required within 3 wk. of slaughter. Positive flocks are re-tested and can only be conditionally moved to slaughter. In the UK Food Chain Information is supplied to livestock processors unless stock is inspected on farm. For example, NTS status, although not time off feed, or membership of an assurance scheme, has to be provided prior to slaughter to allow HACCP managers to manage positive lots. NTS prevalence in meat and poultry is low.

In the USA, on farm prevalence reductions can include use of vaccines, probiotics and organic acids in feed and if preventive controls are not practiced, testing birds and scheduling of processing is recommended. PSs have been applied at livestock slaughter. Poultry products have been those

insufficiently compliant and also linked with increasing numbers of salmonellosis cases and a rebound in SE cases. Applying a risk-based approach the focus of FSIS has recently changed to include all poultry types and to move from PSs for carcasses to PSs for products post-fabrication to reflect the changing retail supplies and consumer exposure and the performance targets and sampling plans made more stringent. Establishment performance in verification testing may be made available publicly. In categorising slaughterhouse performance detection of serotypes of human importance is considered. These are works-in-progress.

Fresh produce, both local and imported, has increased in importance in foodborne transmission of salmonellosis in the USA. A Produce Safety Rule has been introduced with the recent FSMA where the whole food chain beginning at the farm will be required to meet science-based minimum standards at optimal points for risk reduction. This is a recent development to be progressively implemented based on priority risk categorisation of produce types and progress will be monitored by extensive targeted surveillance testing. Some RTE products e.g. nuts have process criteria of a 4-5 log₁₀ NTS reduction. Requirements for sprouted seeds in the FSMA include measures for prevention of seed contamination, in process test and hold programs for pathogens and environmental testing for *L. monocytogenes*.

NTS in dairy products remain a food safety risk where raw milk and dairy products are consumed. The EU permits the sale of these products and regulations include hygiene based controls and hygiene criteria for raw milk, raw milk for direct consumption, and raw milk for manufacturing. Raw milk products must be labelled advising of risks associated with consumption. The presence of NTS in dairy foods appears to be low. NZ has recently allowed raw milk to be sold directly from registered farms or home deliveries under a new regulation that requires hygiene measures, temperature and time controls, performance based testing, and labelling with identification, use-by date, storage conditions and hazard warnings.

Campylobacteriosis

The UK and NZ have very similar overall strategies for *Campylobacter* focused primarily on chicken meat. Both countries set health goals that are further defined for priority foods and are articulated as performance targets to guide industry and for use in regulatory oversight. The main elements of these strategies are targeted quantitative hazard- and risk-based controls along the poultry chain, monitoring performance in meeting targets, safe food handling, and implementing these controls with commitment from all sectors involved. Success has been achieved more quickly in NZ that has the advantage of use of chemical decontamination during processing and was able to engage their industry made up of a few major companies. NZ invested in preliminary risk management activities to guide their strategy such as risk assessments, attribution studies of food source, reservoirs and amplifying hosts combined with molecular typing to clarify transmission pathways, and combined this with risk assessments and cost-benefit analyses of interventions. Risk studies have been carried out in the EU and in addition the countries draw on the work and tools available from Codex/FAO/WHO.

All countries recommend voluntary measures on farm including on farm biosecurity, hygienic harvest (catching and depopulation) and transport, and controlled processing. Attention is paid to packaging of raw chicken, leak proof packaging in NZ, and in the UK some retailers have taken up double bagging. Non-chemical treatments were investigated in the UK such as steam and ultrasound and blast freezing. In their strategies a processor can decide on control options appropriate for their establishment as long as they meet the *Campylobacter* performance target expressed as a quantitative food safety criterion for carcasses at the end of processing. In the UK, the initial target was to lower the prevalence of *Campylobacter* in chicken and had little success. This has been refined to a more risk based

approach of lowering the prevalence of birds with the highest counts that are estimated to present the greatest risk. Again progress has been slow and greater commitment has been sought from all those involved in the food chain. In the USA, performance standards for *Campylobacter* and NTS were changed to include fabricated and comminuted products found to most accurately represent consumer exposure and the performance levels and sampling plans made more stringent to achieve levels assessed to result in acceptable levels of attributable illnesses following consumption of the products. The changes in the USA have been too recent to measure success. Iceland has had notable success with its reduction strategies for campylobacteriosis in chicken that essentially is based on market incentives for processors using performance targets. All carcasses from positive flocks or slaughter batches have to be frozen or heat treated decreasing market value.

Raw fluid milk and raw milk cheeses are attributed among common food vehicles for campylobacteriosis in the USA. Control is hampered by the legalisation of these foods in many states as well as the illegal production and sale or importation of these products often as ethnic specialties, and due to the select group within the population exposed. The regulators are working with specialty cheese processor groups to improve implementation of hazard analysis and risk preventive measures.

All countries invest in extensive consumer information and education activities. Those with successful programs have residual levels of campylobacteriosis and further sources of transmission are being sought.

Listeriosis

In each country the pattern of listeriosis, at risk groups and the main foods attributed have changed over time. There are various possible explanations: successful targeted control programs, changing demographic and socio-economic factors and food supplies, and the ability to investigate *Listeria* has been greatly improved by enhanced epidemiological investigation and molecular and WGS typing.

All countries require RTE food manufacturers to have HACCP based food safety programs that essentially include product formulation, processing, ingredient control, worker training, building design, sanitation and monitoring and record keeping as well as mandated date labelling. Large manufacturers and high end retailers have been successful in producing food with very low prevalence at the point of manufacture and a common focus is now on post-manufacturing risk management. Countries are cautious in setting health targets realising the pressures of at risk groups increasing and the availability of chilled RTE food that will support growth expanding. The USA reacted to its first listeriosis crises by setting a zero tolerance for *L. monocytogenes* in post-lethality treated RTE foods. The UK and NZ have more recently adopted a risk-based approach with food safety criteria based on the ability of a RTE food to support *Listeria* growth during its shelf life. All require environmental testing and the UK had more stringent sampling plans for *L. monocytogenes* in food for infants and foods for special medical needs.

In the UK, older adults and immune-compromised persons both in the community and in care, pregnant women from ethnic groups, and poorer communities often obtaining food from small to medium enterprises manufacturing and retailing riskier foods, have been identified at most risk. The UK strategy is to improve the compliance among those providing food for these groups and education and information materials for the groups themselves. Guidelines for those preparing and serving food to institutionalised persons have recently been prepared and means to reach those living out of care is being sought. Further it has been observed that establishments in this category and enforcement officers have poor understanding of the newer standards for *L. monocytogenes* based on potential for growth. This had been identified as a further need in training programs. In the USA, the Food Code had been amended to provide additional requirements in food service such as prevention of *Listeria*

biofilms in the food service environment, the need to disassemble and scrub equipment regularly (4hr.) and to rotate sanitisers to avoid bacterial resistance. The FSIS is exploring further measures that can be taken at retail.

In the USA, fruits have emerged and dairy foods remain as the most important foods in food attribution studies and outbreaks have increased in size and distribution with changing food supply chains. Dairy products remain problematic due to the consumption of raw milk products and non-regulated processors and vendors. In addition, the potential for survival of *L. monocytogenes* in cheese under the 60 dy. aging rule has been challenged and regulators and industry are working to resolve the issue. The Produce Safety rule recently introduced will include control measures for *Listeria* and further risk assessments are in progress e.g. used of manures as soil amendments. Requirements for sprouts have been mentioned above. The USA has experienced listeriosis outbreaks caused by “novel” foods e.g. caramel toffee apples and stone fruit, which emphasises the potential for this ubiquitous environmental bacterium to find a niche in foods provided the conditions are favourable for survival and/or growth.

NSW current situation

Pathogen reduction strategies

The most striking differences in risk reduction approaches successfully implemented in the USA, UK and NZ is the overall risk management approach and making use of food safety metrics to set performance targets. This is particularly apparent for the zoonotic pathogens.

The pathogen reduction approaches in the USA, UK and NZ are designed to meet foodborne illness health goals for the country. There were no equivalent goals in Australia identified. The NSW Government has taken a significant step in setting its own health goal of reducing foodborne illness by 30%. For the NSW FA risk managers to implement targeted risk reduction strategies to meet this higher level goal, similar to the approach in the reviewed countries, it would be necessary to further define a realistic health target for each of its priority foodborne illnesses and their contribution to the overall 30% target. The relevant agencies in the countries reviewed, have developed targeted strategies to meet these goals and measure progress against respective baseline foodborne illness rates. Currently this is not possible in NSW as there is no surveillance of campylobacteriosis and there is limited current food and reservoir attribution data other than from outbreak investigations and these cases represent a small proportion of the total foodborne salmonellosis and campylobacteriosis cases reported.

The agency strategies are based on risk, evidence and science, and are implemented using a systematic risk management framework. They rely heavily on data on foodborne illness and food source attribution, understanding the food-pathogen pathways, and quantification of the contribution of activities through chain to the final level of health risk using risk assessments. In this way they are able to estimate the potential reduction in human illness associated with specific foods and specific interventions and to prioritise activity to maximise the overall contribution to meeting health goals. To follow their example, the NSW FA would require significantly more information than that identified in this review and need to apply it in a more systematic framework with a focus on risk and quantifiable measures.

This report captured data in NSW from available reports; however, there were activities in progress in NSW and other jurisdictions and within industry that were not captured and data from which could contribute to approaches similar to those taken by the reviewed agencies mentioned. Food source attribution studies are underway in Australia and may require further support to produce timely results. There is an option to translate data from national databases or from studies in other States

and Territories although this would need to be a valid translation. The NSW FA has been very proactive in conducting programs for verification testing, monitoring and surveillance of contamination of a variety of foods produced under the Regulation. The number of samples tested has been small for some food groups using this approach and may not be state-wide. Mandatory regular testing in the countries reviewed provides data on current food chain performance and contamination levels. The Key Performance Indicator Program for chicken meat is an initiative identified that should generate important data for that food group provided all establishments participate. Performance targets for *Campylobacter* in chicken at the end of processing that appear to be in progress should be risk based.

Quantitative risk assessment outcomes are widely used internationally and the NSW FA has been proactive in underpinning their Food Safety Schemes with assessments of risk. Some Australian risk assessments identified did not cover the whole food chain, lacked data, or were hazard identification studies. Proposed NSW FA research with industry groups such as AECL should enhance the risk assessment for eggs allowing a clearer picture of the role of on farm control measures. The countries reviewed are incorporating molecular characterisation of pathogens and a similar approach would provide an opportunity to strengthen these assessments.

Notwithstanding the success of some targeted programs reviewed, they made only a contribution to the impact on the specific rates of illnesses commonly transmitted by food. Countries are seeking further measures to achieve the health goals required. This applies to Australia where for example 77% campylobacteriosis were estimated to be foodborne and 30% of foodborne cases were estimated to be linked with consumption of chicken, suggesting there many other infection sources requiring intervention.

Salmonellosis

There are many similarities as well as differences between the NSW FA Food Safety Schemes and regulations in the reviewed countries. The NSW FA NTS strategy includes control of NTS in shell eggs, microbiological monitoring, training of food retailers and improved genotyping which in the absence of detail indicates a focus on eggs.

It has been argued it is difficult to compare NTS control strategies in SE endemic areas due to the characteristics of SE not endemic in Australia. However, this situation has changed as SE has come under control and other serotypes are proportionately increasing and in the USA there has been a rebound where chicken meat has increased in importance in SE transmission so that the scenarios are not so different. In the EU there has been a move to risk-based regulation targeting “regulated” serotypes while maintaining the same requirements. This risk-based approach to monitoring could be considered by the NSW FA as some of the most commonly isolated NTS types in raw foods such as chicken meat are not common in human infections.

The UK and the USA maintain the same control approaches for NTS in eggs as implemented for SE that include control of transmission from breeding flocks, on farm and post-harvest controls, and they are exploring further on farm control measures for all NTS types. On farm controls are not given the same level of importance in Australia; however, research in egg production should help provide better grounds for this. The main difference identified between strategies in the UK, the USA and the NSW situation is setting risk-based performance targets for NTS and mandatory testing programs to demonstrate compliance for flocks and eggs, and flow on corrective actions to prevent contaminated food entering the marketplace. The UK/EU focus is on farm with breeder and layer flock prevalence limits and testing programs. The USA expectation is controls should be equivalent to NTS reduction achieved by egg pasteurisation either through on farm measures and flock and egg testing programs

or a pasteurisation treatment. These established limits guide industry risk managers, provide incentives, and support regulatory oversight. Multiple interventions through chain have provided the best overall outcome in achieving the health goals. Some interventions have been singled out as having significant impact in achieving targets. In the UK/EU and USA uptake of vaccination of poultry (mandated in some EU Regs and UK farm assurance schemes country) results in reduction of flock prevalence for NTS or a serotype and this is a voluntary option in the USA, refrigeration prevents NTS growth particularly when internalised and use of pasteurised egg products in food service lowers attribution of certain raw egg-based dishes e.g. desserts in restaurants. UK farmer and industry quality assurance programs that may have more stringent standards are an important element in the success of control strategies.

The approaches to control of NTS chicken meat in the UK and USA are similar to that for eggs where the main difference from NSW is again the use of performance targets. The UK has broiler flock prevalence targets and both countries have processing targets determined to reduce prevalence and contribute to lowering illness from consumption of these products. The USA has reviewed which meat and poultry products are associated with health risk and adapted process verification programs accordingly and considered the need for labelling with safe handling and cooking instructions e.g. minced beef, chicken post-fabrication, NRTE products. The USA has the benefit unlike the UK of being able to use chemical decontamination to reduce NTS levels.

In the USA, fresh produce (seeded vegetables) have become the most frequently attributed food in salmonellosis cases. These have included both local and imported product where large production volumes were widely distributed. Australia has now experienced similar outbreaks. The USA has introduced a new Produce Rule that is still a work-in-progress although the whole food chain will be required to implement hazard-based and risk prevention programs. The NSW FA is also collaborating externally on food safety and plant products and would be advised to be aware of developments in other countries.

Campylobacteriosis

The risk reduction approaches for campylobacteriosis in the UK, USA and NZ have been primarily focused on chicken meat although NZ, that has been the most successful, is looking for additional transmission routes to further reduce the incidence. Similar to salmonellosis strategies the main difference with the NSW approach is to set mandatory performance targets for raw chicken and raw chicken products at the end of processing to drive change that would reduce the rate of illness following consumption of chicken to an acceptable level. The targets include sampling plans and acceptable levels of *Campylobacter* prevalence and/or the prevalence of product with high counts and is applied to carcasses, portions and comminuted products. The targets provide a guide and incentive for industry who are able to choose their risk management options on farm, during transport and during processing with supporting guidelines. In NZ repeated failures could result in plant closure. Commitment of those involved in the chicken meat chain and a culture of food safety was identified as an essential element for success in the UK and NZ. Iceland implemented a successful strategy that is also based on use of performance targets and market incentives for processors as all carcasses from positive flocks or slaughter batches have to be frozen or heat treated decreasing market value.

Listeriosis

There are commonalities in the control of *L. monocytogenes* among countries. Existing regulations and control measures have been successfully implemented by large manufacturers and retailers to limit contamination of chilled RTE foods that support *Listeria* growth. Challenges remain in maintaining vigilance of the groups most vulnerable in the community and in care and those who prepare and procure their food. Attention has shifted to the small and medium enterprises manufacturing and

handling risky foods and who also may be the source of food for some emerging high risk populations, e.g. ethnic pregnant women and disadvantaged urban groups, to improve their level of compliance.

Observations of interest in the UK were at risk older adult consumer's poor understanding and response to use-by dates and food processors', retailers' and enforcement officers' poor understanding of the principles underlying standards based on the growth of *L. monocytogenes* and their application. These are areas worthy of noting in NSW. The USA has experienced an increase in reports of listeriosis outbreaks linked with fresh produce and in novel or unexpected foods. The Produce Safely Rule has been discussed.

Technologies and other decontamination measures

Application of technologies and decontamination methods in risk reduction have mostly been used during processing and uptake varies between the countries depending on their permitted use e.g. limited use of chemicals in the EU. An exception is the use of bacteriophages specific for each of the pathogens reviewed that is having a revival in interest with potential use in production animals and birds (zoonotic pathogens), during processing, in products, and for environmental control. There has been an increase in commercial products and their regulatory acceptance and they offer an alternative to use of antimicrobials. There are numerous scientific reports on chemical decontamination, many of which are based on inoculated products and laboratory experiments and remain unproven in situ. Most result in 1-2 log₁₀ reduction of pathogens.

Non-thermal processing technologies have been available for some time. They have the benefits of the same pathogen reduction levels as thermal processing and can result in a better quality product although industry uptake has been slow. The EU has been investing in promotion of these technologies as an alternative to chemical treatments. In the UK, a commercial process using steam and ultrasound has been taken up by industry and reported to reduce *Campylobacter* on neck and breast skin by 80%.

Shell egg decontamination treatments have been investigated although not all result in a NTS reduction equivalent to a pasteurisation process criterion of a 5 log₁₀ reduction as required in the USA and have to be combined with other interventions and refrigeration. There are patented thermal pasteurisation processes using water baths, pulsed light, ultra sound/thermal and radio frequency treatments. Lower reductions of about 2 or 3 log₁₀ reduction are achieved using ionizing radiation, atmospheric cold plasma or microwave technology.

Conclusions

The approach to reduction of the risk of NTS, *Campylobacter*, *L. monocytogenes* in food in the USA, UK and NZ, and NSW and the approach of Codex were extensively reviewed. There are similarities in the pathogen/food issues. There are 3 general scenarios observed. The zoonotic foodborne pathogen (NTS and *Campylobacter*)/pathways fall into 2 of these: primary products that have had mandated performance limits for a long time, and are now of lesser importance in illness transmission, and, those with no equivalent performance limits historically, frequently attributed to illness now, and being addressed by implementation of mandatory performance limits. The third scenario includes *L. monocytogenes* for which performance limits were established and it has come under control in the pathways initially identified and by large manufacturers, and for which control approaches are being re-focused on post-manufacture handling, changing at risk groups and other foods. While the programs in these countries were generally showing evidence of success the level of success and the speed in achieving it differs.

The most outstanding difference between the current NSW situation and the reviewed countries is the overall regulatory approach. The overseas countries have established national health goals for

specific foodborne illnesses and their agencies have designed targeted risk- and evidence-based pathogen reduction strategies to be implemented in a systematic management framework to achieve these goals. This is closely aligned with the more recent works of Codex. Maintenance of basic hazard and hygiene controls is mandatory and mostly, participants in the food chain could choose their pathogen control measures with regulatory guidance as in NSW. The difference is the control measures have to result in a performance level that would meet mandatory quantitative targets set at effective risk reduction points in the food chain. The performance targets serve several purposes, to guide and incentivize industry risk managers, for regulatory process verification and monitoring, to measure progress and to inform review and the need for modification. In the event of failures corrective actions are enacted to protect the food supply.

While there are testing programs and test limits in the NSW FA Food Safety Schemes Manual, many are for processed/manufactured foods, and are hygiene criteria or often food safety criteria for *L. monocytogenes*. There are recent initiatives for process verification testing for chicken meat where results are compared with 2006-2008 surveys to rate performance. There is an opportunity to establish risk-based food safety performance targets to guide pathogen reduction strategies.

The NSW Government has been forward thinking in setting a health goal for foodborne illness; however, for the NSW FA to operationalise this and measure progress further breakdown to specific foodborne illnesses will be required. The NSW FA has been pro-active in basing its Food Safety Schemes on risk assessments. To take a similar approach to the countries reviewed a more risk based and quantifiable approach would be required. The evidence base for this could draw on outputs of existing and planned programs and research, and additional knowledge gaps may need to be filled especially in the areas of disease surveillance, food source and reservoir attribution, understanding transmission pathways from farm to plate, and risk factors.

There were few specific intervention measures that differ from NSW food chain practices. Widespread uptake of vaccination of poultry to control NTS was one and it is to be investigated by the FA together with the egg industry in the Food Strategy. Thermal and non-thermal technologies are effective although uptake varies considerably. These technologies are an attractive option for shell eggs although not all are equivalent to a pasteurisation process criterion as in the USA and the impact on egg functionality is variable. Bacteriophage is attracting increased interest through chain and decontamination using chemical rinses during processing is popular in the USA although restricted in the UK/EU.

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Annexes

Annex 1 FSIS *Salmonella* Action Plan

FSIS *Salmonella* strategy priority actions (FSIS, 2016d)

	Action	Activity	Outcome	Year 1	Year 2
1	Proposed poultry slaughter rule	Modernisation of poultry slaughter inspection	Decrease $\geq 4,286$ illnesses	Fulfilled; implementing plants do their own testing	
2	Sampling related activities	Develop PS for comminuted poultry, ensure all products covered by PSs, develop PS program for pork products	sampling aligned with foodborne illness trends	fulfilled	Proposed PSs for chicken parts and comminuted poultry, surveys for pork
3	New in plant strategies	Inspectors informed of plant performance, make assessments, help identify concerns and direct enforcement action if needed	Focus inspection on prevention and improvement	Fulfilled for comminuted poultry	
4	Directive for sanitary dressing in hogs	Develop verification activity for hog slaughter establishments	Decrease sanitary dressing problem e.g. skin removal, address pork attribution in outbreaks	75%	Draft directive
5	Modify NTS category posting	Investigate evidence for improvement expected with posting names of establishments rated Category 1 and 2 as well as the worst, category 3 on FSIS website	Provide incentive for industry to improve process control.	Proposed 2015	
6	Other PSs	Link NTS PSs to Healthy People 2020 goals e.g. establish standards for poultry (based on RAs), hogs and pork, consider moving window sampling plans	Move agency closer to Healthy People 2020 goals	100%	
7	New enforcement strategies	Investigate links between plant performance, class, enforcement history and sanitary dressing findings particularly class 3 establishments	A systems or overall process approach to reduce NTS issues	Set later	

8	Investigate role of lymph nodes in NTS contamination	Investigate the role of lymph nodes, identify solutions and if warranted test beef and pork tissue	Potential reduction NTS in ground beef and pork	75% ongoing	
9	Pre-harvest	Synthesise information on pre-harvest interventions by FSAS and industry and overcoming regulatory barriers, poultry noted.	Decrease in prevalence or levels of NTS on FSIS-regulated products.	ongoing	
10	Education and outreach tools and resources	Investigated new approaches or routes for food safety messages to the public (more detail, easy access, audience-appropriate)	Decrease salmonellosis	Using social media e.g. webinars, blogs, twitter	

Annex 2 Notes from USA Draft FSIS Compliance guideline for controlling *Salmonella* and *Campylobacter* in raw poultry

These guidelines are provided to support the PR:HACCP and SSOP requirements for poultry processors and summarises points at which *Salmonella* and *Campylobacter* can be prevented, eliminated, or reduced at pre- and post-harvest (FDA, 2015c).

Three integrated approaches are recommended including:

- pre-harvest interventions,
- adequate sanitary dressing procedures at slaughter, and
- adequate sanitary conditions during further processing.

The main approaches to be considered at these points are summarised.

General considerations

1. Implementation of general sanitation programs and hygienic slaughter
2. Lotting practices for traceability and reducing the impact of recalls
3. Use of validated and approved interventions
4. Microbiological sampling and testing to meet minimum requirements of the PR: HACCP Rule to monitor process control and make decisions on process control e.g. ongoing verification testing, statistical process control.

Pre-harvest interventions and management practices

1. Reduce or eliminate *Salmonella* and *Campylobacter* in incoming birds by receiving birds from grow-out farms, hatcheries, and breeder flocks that implement recognized pre-harvest interventions. A multi-hurdle approach is recommended to reduce exposure and colonisation (prevalence and concentration):
 - a. Vaccines
 - b. Competitive exclusion and probiotics
 - c. Organic acids in feed and water.
2. If 1) is not implemented, then test incoming birds and poultry products before entry into the establishment and make processing decisions based on those results. Use the testing to consider implementing scheduled slaughter and modifications to processing plans.
3. Other considerations
 - a. Breeder flock and hatchery - place broiler and turkey chicks from breeder flocks free of *Salmonella* and *Campylobacter* onto grow-out farms,
 - b. Grow-out houses – develop and implement written biosecurity and hygiene plans,
 - c. Bedding, feed and water should be *Salmonella* and *Campylobacter* free,
 - d. Transportation practices to minimise cross-contamination.

Adequate sanitary dressing procedures at slaughter – intervention points

1. Scalding to reduce levels of *Salmonella* and *Campylobacter* can be used as an intervention if properly maintained
2. Carcass rinses or sprays to reduce contamination
3. Chilling to prevent microbial growth

Further processing

1. Ensure incoming product produced under good sanitary procedures,
2. Ensure best practice, sanitation and minimise cross-contamination,
3. Additional attention to non-intact parts and products, use of antimicrobials is recommended and guidance on their individual pros and cons, typical parameters and

scientific references are provided for: inorganic and chlorine-based, acidified sodium chloride, trisodium sulphate, quaternary ammonium compounds, organic acids and oxidisers), bacteriophages, electrolysed oxidising water, crust freezing, high pressure, cryogenic freezing, irradiation,

4. Provision of validated cooking instructions so that the endpoint temperature and, if applicable, rest time will ensure a 7 log₁₀ reduction of *Salmonella* or other reduction consistent with requirements for producing ready-to-eat poultry products (9 CFR 381.150),
5. Product appearance- if RTE but has a cooked appearance, conspicuous labelling alerts required for consumers.

Annex 3 FDA FSMA Produce Safety Rule

The following are key points highlighted by FDA in the FSMA Produce Safety Rule in relation to pathogen reduction (FDA, 2015f).

- Agricultural water quality. Two sets of criteria for microbial water quality have been established based on generic *E. coli* as indicators of fecal contamination:
 - Qualitative- not detectable in water used for direct contact (washing hands, surfaces, produce etc.), and,
 - Qualitative- for agricultural water (irrigation etc.) includes a geometric mean count (≤ 126 cfu/100mL) and also a statistic threshold of samples (≤ 410 cfu/100mL) that provides for variability and occasional high levels due to adverse conditions. The FDA has provided risk based sampling plans (e.g. surface and ground water, treatment) and is developing online tools to manage data;
- Biological soil amendments. The FDA will establish standards aiming to quantify amendment use and human illness. FDA is deferring its decision on an appropriate time interval between the application of untreated biological soil amendments of animal origin, including manure, and harvest of produce, until completion of their risk assessment. Included are microbial standards for amendments of animal origin: *L. monocytogenes* not detected in 5g or ml, NTS not detected using a method that can detect 3 MPNs per 4g or ml.
- Sprouts. New requirements have been included:
 - measures to prevent the introduction of pathogens into or onto seeds or beans used for sprouting, in addition to treating seeds or beans that will be used for sprouting (or relying on prior treatment by the seed/bean grower, distributor, or supplier with appropriate documentation);
 - Testing of spent sprout irrigation water from each production batch of sprouts, or in-process sprouts from each production batch, for certain pathogens (NTS, O157 STEC) and applying a test and hold strategy;
 - Testing the growing, harvesting, packing and holding environment for the presence of *Listeria* spp. or *L. monocytogenes*; and,
 - corrective actions to be applied if spent sprout irrigation water, sprouts, and/or an environmental sample tests positive.
- Domesticated and wild animals. All measures reasonably necessary are required to identify intrusion and if detected to stop harvest. If detected during growing measures are required to assist later harvest decisions.
- Worker training and health and hygiene. Workers are to be trained in hygienic handling in the field and processing, personal and visitor hygiene, appropriate for their responsibility.

- Equipment, tools and buildings. Standards relate to prevent these items leading to contamination of produce e.g. appropriate storage, maintenance and cleaning of equipment and tools.

Annex 4 Key finding of the FSIS Comparative Risk Assessment for *Listeria monocytogenes* in Ready-to-eat Meat and Poultry Deli Meats (FSIS, 2015a)

Interventions for *Listeria monocytogenes* in Ready-to-eat Meat and Poultry Deli Meats and predicted reductions of listeriosis illnesses caused by consumption of contaminated deli products prepared or sliced in retail delis in the USA (FSIS, 2015a)

Intervention	Approximate reduction of illnesses
Storage temperature. RTE foods supporting <i>L. monocytogenes</i> growth should be stored at $\leq 5^{\circ}\text{C}$ (Food Code 2013)	9%
Growth inhibitors. Reformulate product to include inhibitors; could depend on shelf life or if insufficient concentration used to preserve flavour	96%
Control cross-contamination. Elimination all points of cross-contamination, particularly slicers; also proper handling, cleaning, sanitising and glove use	34%
Control contamination at source. Eliminate environmental niches; reduce incoming product (both supportive and not supportive of growth) contamination by 50%	22%
Continue sanitation. Eliminate <i>L. monocytogenes</i> on food-contact surfaces; glove use	5% (gloves use)

Annex 5 *Listeria* Rule

Three alternative treatment approaches for control of *L. monocytogenes* are provided:

Alternative 1 – validated post-lethality treatment to reduce or eliminate *L. monocytogenes* and suppress or limit growth,

Alternative 2 – either option in Alternative 1,

Alternative 3 – rely on sanitation programs only.

Choosing Alternative 3 requires justification for why Alternate 1 or 2 are not required and must include a testing program for contact surfaces and corrective action and establishments may not release into commerce product that has been in contact with *L. monocytogenes* contaminated surfaces without reprocessing the product.

Annex 6 British Lion Code of Practice for commercial eggs in the UK (Lion, 2013)

The British Lion Code of Practice for eggs main requirements are as follows:

- registration and traceability for the entire production chain including feed,
- higher animal welfare requirements than required by law and registration with a veterinarian required,
- *Salmonella* vaccination against SE and S. Typhimurium for all birds destined for egg-producing flocks,

- control and NTS testing of all flocks in the egg production chain, NTS testing of farm, housing and packing centre environments in excess of the National Program with corrective action protocols,
- feed control to meet specified standards, includes heat and/or acid treatment of breeder feed,
- egg stamping with farm code and production method,
- egg testing: at least 20 eggs/ quarter from each farm supplying a packing centre,
- time and temperature controls: egg storage at <20°C on farm, egg transfer to packing centre at least twice/wk. and eggs kept constantly below 20°C, egg cool chain kept at 5-20°C,
- 'Best before' date on shell and egg pack,
- independent auditing,
- business operation including environmental policy, crisis plan and staff training in hygiene, bird welfare and vaccination,
- HACCP controls in packing centres with written schedules for hygiene, rodent control and biosecurity,
- retailers must advise customers to store eggs constantly below 20°C away from heat and sunlight and must sell in strict rotation.

Annex 7 Microbiological criteria for meat and poultry production and processing in the UK (UKFSA, 2015)

Microbiological criteria required for food safety and hygiene compliance for meat and poultry processing and RTE foods in the UK (UKFSA, 2015) and Regulation (EC) No 2073/2005 (<http://faolex.fao.org/docs/pdf/eur61603.pdf>)

Species and product	Pathogen	Sample number (frequency depends on compliance/risk)	Food safety/NTS process limits
Food safety criteria: if unsatisfactory remove or do not place on market			
Minced meat and meat preparations intended to be eaten raw e.g. steak tartare; market during shelf life	NTS	5 x 25g	NTS* ND
Minced red meat and red meat preparations intended to be eaten cooked	NTS	5 x 10g	NTS ND
Mechanical separated meat	NTS	5 x 10 g	NTS ND
Processed meat products intended to be eaten raw	NTS	5 x 25g	NTS ND
Fresh poultry meat (hens, broilers, breeders, turkeys)	<i>S. Enteritidis</i> and <i>S. Typhimurium</i>	5 x 25g	NTS ND
Poultry meat products intended to be eaten cooked	NTS	5 x 25g	NTS ND
Minced poultry meat and preparations intended to be eaten cooked	NTS	5 x 25g	NTS ND
RTE meats that do not support growth of <i>L. monocytogenes</i> or	<i>L. mono.</i> count	5 x 25g	<i>L. mono.</i> < 100 cfu/g

have evidence growth will not reach > 100 cfu/g before the end of shelf life			
RTE meats that support growth of <i>L. monocytogenes</i> and have no shelf life assessment data	<i>L. mono.</i> count	5 x 25g	<i>L. mono.</i> ND
RTE foods for infants and special medical purposes	<i>L. mono.</i>	10 x 25g samples	<i>L. mono.</i> ND 10/10
RTE food able to support growth of <i>L. monocytogenes</i> other than for infants and special purpose	<i>L. mono.</i>	During shelf life 5 x 25g At manufacturer 5 x 25g	<i>L. mono.</i> < 100 cfu/g <i>L. mono.</i> ND
RTE foods unable to support growth of <i>L. monocytogenes</i> other than for infants and special purpose	<i>L. mono.</i>	5 x 25g	<i>L. mono.</i> < 100 cfu/g

Process hygiene criteria: if exceeded take corrective action; used in trend analysis

Cattle, sheep, goats and horse carcasses pre-chill	APC# Enterobacteriaceae NTS	NTS swab(excision) 5/session for 10 consecutive sessions (n=50) weekly	NTS: Process cr, < 2/50 +ve
Pig carcasses pre-chill	APC Enterobacteriaceae NTS	NTS (swab) 5/session for 10 consecutive sessions (n=50)	NTS: Process cr. <3/50
Broiler and turkey carcasses post-chill	NTS	15carc. /session to make 5 samples for 10 consecutive sessions (n=50); one sample = 3 pooled neck skins (25g); moving window	Process cr, < 2/50 +ve Food safety cr. for SE and <i>S. Typhimurium</i> ND in 5 samples
Minced and mechanically separated meat	APC <i>E. coli</i>	5 samples/batch/ sampling session	
Meat preparations	<i>E. coli</i>	5 samples/batch/ sampling session	

*NTS = non-typhoidal *Salmonella*; ND = not detected #APC = aerobic plate count

Process criteria limits for APC and Enterobacteriaceae in meat and poultry production

	APC	Enterobacteriaceae	NTS
Cattle, sheep, goats and horse carcasses			
Unacceptable - mean log /number of positives is above	5.0 (4.3)*	2.5 (1.8)	2/50
Acceptable - mean log below	5.0 (4.3)	2.5 (1.8)	
Satisfactory - mean log / number of positives is equal to or below	3.5 (2.8)	1.5 (0.8)	2/50
Pig carcasses			

Unacceptable - mean log /number of positives is above	5.0 (4.3)	3.0 (2.3)	3/50
Acceptable - mean log below	5.0 (4.3)	3.0 (2.3)	
Satisfactory - mean log / number of positives is equal to or below	4.0 (3.3)	2.0 (1.3)	3/50
Broiler and turkey carcasses			
Unacceptable - mean log /number of positives is above			5/50
Satisfactory - number of positives is equal to or below			5/50
Minced and mechanically separated meat	APC: 5/5 < 5x 10 ⁶ cfu/g and 3/5 < 5x10 ⁵ cfu/g <i>E. coli</i> : 5/5 <500cfu/g and 3/5 <50cfu/g		
Meat preparations	<i>E. coli</i> : 5/5 <5,000cfu/g and 3/5 <500cfu/g		

*swab value (excision value)

Annex 8 UK *Salmonella* National Control Programme for chicken flocks (*Gallus gallus*)

UK *Salmonella* National Control Programme for chicken flocks (*Gallus gallus*) sampling strategy (EFSA, 2014)

Production stage	Frequency (Less based on performance)	Sample types	No. samples	Operator voluntary monitoring
Breeder flocks				
Day old chick consignments	all on arrival	Tray or box liners, dead/cull chicks	1 liner/500 chicks up to 10 liners; all dead chick; up to 60 culls	Hatchery debris, fluff, meconium samples etc.
Rearing period	at 4 wk. old and 2 wk. before move to layer phase/laying unit	Boot swabs or composite faeces	Min. 2 pairs boot swabs or composite of 1g samples over rearing area; size based on bird numbers	Rodent droppings, dust, empty housing, transport vehicle samples etc.
Production period	every 2-3wk.	Boot swabs or composite faeces	Min. 5 pairs boot swabs and as above	Hatcher debris, fluff, dust, rodent droppings, transport vehicle samples, extra boot swabs or faeces etc.
Official Control Samples	Twice, usually within 4 wk. of moving to layer unit and last 8wk. production period	Boot swabs or composite faeces		
Broiler flocks				
On farm pre-slaughter	3 wk. before slaughter	Socks/boot swabs	Min. 2 pairs boot swabs over access area or hand drag swabs for <100 birds	Extra boot swabs, litter, dust, rodent droppings, empty housing, transport vehicles samples etc.
Official Control Samples	Annually for 10% holdings of >5,000 birds			
Layer flocks				
Day old chicks	As for breeders	As for breeders	As for breeders	
Rearing period	and 2 wk. before move to laying unit/ start of lay	As for breeders	As for breeders	As for breeders
Production period	At least every 15 wk.	As for breeders	Min. 2 pairs boot swabs or 2x 150g composite faeces representative of the access area	Rodent faeces, environmental, empty house, dust, transport vehicle and egg samples,

Official Control Samples	Annually from 1 flock on all premises with >1,000 birds		2 pair boot swabs/ 2 composite faeces samples, dust sample OR 3 pairs boot swabs / 3 composite faeces samples	
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Annex 9 New Zealand National Microbiological Database requirements for meat and poultry

Sampling programs of the National Microbiological Database for raw meat and poultry in New Zealand (NZMPI, 2015b). Updates to the NMD for 2016 can be found at <http://www.mpi.govt.nz/mpisearch/?site-search=NMD+poultry+Salmonella+data+first+quarter+2013>, cited 29/03/16.

Site, species and product	Frequency	Microbiological analyses
Bovine, bobby calf, caprine, cervine, ostrich and emu carcasses post slaughter and dressing	Weekly	APC*, <i>E. coli</i> NTS (each seasonal sampling window; ostrich/emu each processing week)
Porcine post slaughter and dressing	Weekly	APC, <i>E. coli</i>
Ovine post slaughter and dressing	Weekly	APC
Ostrich and emu carcasses post slaughter and dressing	Weekly	APC, <i>E. coli</i> NTS
Post chill carcasses: bovine, bobby calf and caprine species (not required for hot boning premises)	Weekly, for a 6 consecutive week annual sampling window, at the start of the season	APC, <i>E. coli</i>
Primal cuts: bovine, bobby calf, caprine, and cervine	Weekly	APC, <i>E. coli</i> Diluent remaining after APC/ <i>E.coli</i> test is composited for NTS
Poultry whole carcass rinse (includes chicken with a trial of turkey and ducks in 2016)	Every processing day (3 carcasses x 5 days) over moving window of 3 processing periods (45/15d) or one processing day/week (3 carcasses) for very low throughput premises (9/3wk.)	<i>Campylobacter</i> enumeration and detection for each carcass NTS for 1/3 carcasses

* APC – aerobic plate count; NTS – non-typhoidal *Salmonella*

Poultry (chicken) *Campylobacter* Performance Target (NZMPI, 2015b)

Enumeration Failure: generated upon detection of a value > 6000 cfu/carcass (3.78 log₁₀ cfu/carcass) in:

Standard throughput: 7 or more individual carcass samples in a 45 sample, 3 successive processing periods moving window; OR

Very low throughput: 2 or more individual carcass samples in a 9 sample, 3 successive processing periods moving window.

Detection Failure: generated upon detection of 2.30 log₁₀ cfu/carcase or greater in:

Standard throughput: 30 or more individual carcass samples in a 45 sample, 3 successive processing periods moving window; OR

Very low throughput: 6 or more individual carcass samples in a 9 sample, 3 successive processing period moving window.

Annex 10 Regulated Control Scheme requirements and specifications of raw milk under the New Zealand Raw Milk for Sale to Consumers Regulations 2015

The requirements for Regulated Control Schemes for raw milk (NZMPI, 2016d) that differ from raw milk to be further processed include;

- a) raw milk must be maintained at a temperature at or below 6 °C at all times between initial cooling and delivery to a consumer;
- b) sufficient sampling and testing must be undertaken to confirm that raw milk is being harvested and processed under hygienic conditions and that food safety standards are routinely met;
- c) the frequency of sampling and testing for some microbiological parameters is performance based and recognises consistent conformance;
- d) the maximum time from harvesting the milk through to delivery to, or receipt by, the consumer is 30 hours;
- e) the use-by date for raw milk is 4 days after the commencement of milking for the oldest milk in the lot;
- f) the verification audit and raw milk farm dairy assessment frequencies are performance based rather than fixed.

Requirements on labels of Regulated Control Schemes milk that is packaged or printed labels for milk taken from a vending machine:

- a) Statement the container contains “raw (unpasteurised) milk”
- b) Show “use-by-date”
- c) Lot identification of the milk
- d) Specified storage directions
- e) Specified warning information
- f) Name and address of supplier

A dairy operator must ensure a consumer cannot place an order for Regulated Control Schemes milk by any means without first acknowledging that they have read or been given the warning information. Any advertising material for Regulated Control Schemes milk must include the specified warning information.