NSW Food Authority

safer food, clearer choices

Risk assessment policy

A policy for the development and utilisation of risk assessment by the NSW Food Authority

December 2009

NSW/FA/CP041/1001

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1. Introduction - establishing a risk assessment policy

The NSW Food Authority (the Authority) develops food regulatory measures for industry to produce safe and correctly labelled food by:

- contributing to national food policies and standards
- establishing NSW food safety regulations and food safety programs
- developing food laws in consultation with stakeholders, and
- auditing, inspecting and enforcing food regulations

In developing food safety regulations, the Authority is required to base control measures on the best available science (as detailed in the key objectives of the Authority's Science strategy) to:

- bring the best science and science advice (as one input) into decision making
- build the standing of science and knowledge in the agency and its stakeholders, and
- support delivery of the targets set out in the Authority's overall corporate plan and inform the on going development of the corporate plan.

Part of applying science to the decision-making process is to base new food regulations on the application of risk assessment. The Codex Alimentarius Commission (Codex) defines risk assessment as a scientifically-based process forming one component of the overall risk analysis framework, which also includes risk communication and risk management. The Authority is required by the NSW *Food Act 2003* to undertake:

an assessment of food safety risks in the industry or sector of industry to which the food safety scheme relates in accordance with national and international standards for risk assessment

While this requirement applies to the development of new food safety schemes, the Authority's strategy as a science-based organisation means that risk assessment or risk profile work may be applied to food commodities not covered under a food safety schemes and in response to urgent issues where there is uncertainty on the impacts of hazards on human health.

The Codex document *Working principles for risk analysis for food safety for application by governments* (Codex, 2007a) establishes that a risk assessment policy should be included as a specific component of risk management. As such, the Authority has developed this risk assessment policy to ensure that future risk assessment work is systematic, complete, unbiased and transparent.

This risk assessment policy identifies the Authority's processes for conducting risk assessment, how it will be used, reviewed and updated in line with the international principles established by Codex.

2. A functional separation of risk assessment and risk management

Codex recommends a functional separation of risk assessment and risk management as far as practicable (Codex, 2007a), in order to:

- ensure the scientific integrity of the risk assessment
- avoid confusion over the functions to be performed by risk assessors and risk managers, and
- reduce any conflict of interest

The Authority aligns with this Codex principle by having the Authority's Science and Policy Branch responsible for conducting risk assessment work, the risk management control measures implemented by the Compliance Investigation & Enforcement Branch and risk communication undertaken by the Communication & Corporate Resources Branch.

However, Codex also recognises that risk analysis requires interaction and consultation between risk managers and risk assessors as an essential element in developing a meaningful risk assessment and the practical application of risk management options for ensuring food safety.

2.1 Types of risk assessment

There are two main types of risk assessment, which the Codex publication *Principles and guidelines for the conduct of microbiological risk assessment* (Codex, 1999) defines in the following way:

- quantitative risk assessment - which provides a numerical expression of the risk and an indication of the attendant uncertainties (eg number of illnesses per year)
- qualitative risk assessment - based on data which, while forming an inadequate basis for numerical risk estimations, nonetheless, when conditioned by prior expert knowledge and identification of attendant uncertainties permits risk rankings or separation into descriptive categories of risk (eg high, medium, low risk)

In addition to these forms of risk assessment, Codex (2007b) also defines a risk profile as:

- a description of a food safety problem and its context that present in a concise form, the current state of knowledge related to a food safety issue, describes potential risk management options that have been identified to date, when any, and the food safety policy context that will influence further possible actions.

Where risk management action is needed, the risk manager may request a risk assessment to provide appropriate scientific information on hazards and their risks. In other cases, a risk assessment may not be needed or may not be possible due to a lack of data, and a less extensive assessment (eg limited to an exposure assessment or a hazard characterisation) may suffice. Other options are to gather more information to better inform preliminary risk management activities, such as establishing a survey to collect more data or conduct research to further investigate an issue.

The form of risk assessment/risk profile the Authority will undertake in each situation will be guided to a certain extent by the purpose of the work and the availability of resources and data. However, the Authority will ensure that the risk assessment or risk profile is fit for its intended purpose in each instance and will follow the established international standard for risk assessment.

Codex (1999) defines risk assessment as a scientifically based process consisting of four steps:

- hazard identification – the identification of biological, chemical, and physical agents capable of causing adverse health effects and which may be present in a particular food or group of foods.
- exposure assessment – the qualitative and/or quantitative evaluation of the likely intake of biological, chemical, and physical agents via food as well as exposures from other sources if relevant.
- hazard characterisation – the qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with the hazards. For the purpose of microbiological risk assessment the concerns relate to microorganisms and/or their toxins.
- risk characterisation – the process of determining the qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based in hazard identification, hazard characterisation and exposure assessment.

For the purposes of the Authority's risk assessment policy, the term risk assessment will be taken including all approaches used in assessing foodborne risks to consumers from all hazards of a microbiological, chemical and physical nature. Regardless of whether the Authority uses the approach of conducting a qualitative risk assessment, quantitative risk assessment or a risk profile, it will do so in accordance with the four steps of risk assessment (hazard identification, exposure assessment, hazard characterisation and risk characterisation) to establish a consistent format and align with international best practice.

2.2 Scope and purpose

Before undertaking any risk assessment work, the Authority will ensure that there is a clear purpose and scope stated. The process of establishing the scope may involve the development and elaboration of specific risk management questions that the risk assessment will be designed to answer. The development of these questions should involve both risk assessors and risk managers to ensure that the end result will address the need.

For each individual piece of risk assessment work, any impacting factors that may affect the scope, data analysis, interpretation and presentation of risk assessment results should be explicitly recognised and documented up front. In addition, defining an endpoint is critical to ensuring the risk assessment is completed in a timely manner, and to ensure that the risk management issues are adequately addressed.

In addition to the initial consultation for establishing the scope and purpose of the risk assessment, the Authority will ensure that there is communication between risk assessors and risk managers throughout the risk assessment process. This will help the process track smoothly and attempt to avoid any surprises at the conclusion of the risk assessment. This consultation will also help determine if the scope of the risk assessment needs adjusting. If circumstances do arise during the risk assessment that require new assumptions and a revision of the scope and purpose, this should be fully documented to protect the scientific integrity of the risk assessment process and allow full transparency.

Information that should be documented prior to the commencement of a risk assessment includes:

- scope and purpose of the risk assessment
- description of the specific risk management issue and the questions the risk assessment should answer
- the type of risk assessment/risk profile to be conducted, expertise needed, and resources allocated
- how the outputs of the risk assessment will be used by risk managers
- timelines for milestone reporting, completion targets, peer review
- criteria to validate the risk assessment outcomes and determine scientific and technical adequacy of the risk assessment, and
- identification of future data needs

2.3 Forming the risk assessment team and using expert knowledge

The Authority recognises that ideally, a multi-disciplinary team should be assembled to undertake risk assessment work, particularly if the scope of the risk assessment includes modelling of the production-to-consumption food chain. To maintain the functional separation of risk assessment from risk management, the Authority will predominantly use the resources from within the Science & Policy Branch, however the risk assessment team may also need to call in resources from other branches within the Authority or external to the Authority (eg epidemiological and toxicological expertise) from government departments or consultants to assist in conducting the risk assessment work.

3. The Authority's process for undertaking risk assessment

3.1 Sources of data

Risk assessments can be very resource intensive in terms of scientific input and time, therefore, wherever possible the Authority will use previous risk assessment and risk profile studies to base its own risk assessments on. Codex suggests that risk assessments should include quantitative information to the greatest extent possible in the estimation of risk (Codex, 1999), but it may be necessary to use qualitative data to fill data gaps. Codex also emphasises the importance of using high quality information when conducting a risk assessment, in order to reduce uncertainty and increase the reliability of the risk estimate. Also, any risk assessment work should be based on scientific data that is most relevant to the national context, taking into account the relevant production, storage and handling practices used through the food chain (Codex, 2007a). The Authority will give priority to peer reviewed Australian risk assessment studies, as this data will most closely reflect the NSW situation and food safety practices that occur within the Authority's jurisdiction.

The Authority will primarily consider the risk assessment work undertaken by the national food standards setting body Food Standards Australia New Zealand (FSANZ), however the Authority has in the past also utilised work funded through industry peak bodies such as Dairy Australia, Meat & Livestock Australia (MLA) and the Australian Egg Corporation Limited (AECL) who have commissioned independent research organisations to undertake risk assessments on their behalf. In addition, the state and territory food regulatory jurisdictions have also undertaken some limited risk assessment/risk profile work which will also be utilised when appropriate.

The Authority will also utilise international risk assessment reports, acknowledging the different influences that may occur where these studies originate. The Authority will take into account the relevant information and guidance obtained from risk assessment work undertaken by organisations such as Codex, Food and Agriculture Organization (FAO), World Health Organization (WHO) including the relevant expert groups such as the Joint FAO/WHO Meetings on Microbiological Risk Assessment (JEMRA), Pesticide Residues (JMPR) and Food Additives (JECFA). The Authority will also utilise data from other relevant international and national organisations such as the US Food and Drug Administration (FDA), European Food Safety Authority (EFSA) and New Zealand Food Safety Authority (NZFSA) and peer reviewed journal articles and books.

In all cases, the source data will be critically evaluated by the Authority to ensure it is unbiased and scientifically valid to the NSW food industry context.

3.2 Risk assessment tools

The Authority has a number of tools (described briefly in Appendix 2) which it may use to generate risk assessment outcomes in the form of either a qualitative or quantitative risk estimate. While these tools are useful in helping to generate risk assessment outcomes, the Authority recognises that the effectiveness of these tools is limited by the quality of data and/or the assumptions made in the absence of quantitative data, being fed into these tools.

3.3 Handling uncertainty

Even with all the potential data sources listed above, there will be issues where the relevant data to undertake a quantitative risk assessment is not available, or where there is a high degree of uncertainty in the data that does exist. This will often be the case in assessing chemical contamination hazards where a great deal of uncertainty exists surrounding tolerable levels of consumption.

When data gaps exist, estimates and assumptions may have to be made based on expert knowledge or extrapolation from the relevant information available. In order to ensure public safety to the greatest extent possible, this may result in inherently cautious assumptions being made or an additional 'safety margin' being incorporated. In all instances, any assumptions the Authority makes during the risk assessment will be fully documented and the impacts of key assumptions outlined. Should new data become available that demonstrates that previous assumptions were inaccurate, this should trigger an update of the risk assessment.

3.4 Presentation of risk assessment outcomes

While it is preferable to determine the format of the risk assessment outcomes prior to commencing the work, a major determinant in what outcomes are possible will be the availability of appropriate data. The Authority's preferred approach is the generation of a quantitative risk estimate, but this may not always be possible and a qualitative risk estimate may be suitable to address the risk management question. While risk estimates may be produced for the general population, it may also be necessary to include additional risk estimates for the most susceptible sub-populations (eg children/elderly). A risk estimate can be expressed in a number of different ways:

- risk per serving of food

- risk per year
- risk per lifetime
- disability-adjusted life-years (DALYs)
- number of illnesses per year in a population
- relative risk (high – low – medium)

While the risk estimate may be presented as a numerical expression, it is important that this is interpreted to achieve transparency and to provide an output that is in an easily understandable form and is useful to the risk managers.

Furthermore, the Authority will attempt to present all risk assessment work in a format that is clear, written in plain language with all technical terms defined, minimises the use of jargon and includes well-designed tables and graphs to summarise the data wherever possible. Although a risk assessment may include information that is quite technical in nature, the Authority will consider presenting the risk assessment in two different formats: a technical report for those with specific technical expertise, and an interpretative summary to assist risk managers and the broader audience to understand the risk assessment. To this end, it may be useful to move technical details to appendices so that they do not distract the reader from the key risk assessment outcomes.

All risk assessment undertaken by the Authority will fully and systematically document:

- all data, assumptions, extrapolations, calculations, technical descriptions and model parameters with assigned values and/or distributions. These will be presented in summary tables or appendices that will allow the reader to follow the logic of the risk assessment in a transparent manner.
- all relevant information on data gaps, uncertainty and variability in the data, acknowledgement of assumptions made, and their influence on the risk assessment outcomes.
- a description of criteria used to assign categories if a scale or ranking system is used to characterise risk assessment parameters.
- a risk characterisation that clearly presents the outcome of the risk assessment process and describes important factors that may alter the risk estimate (eg new knowledge, different assumptions, changes in exposure pathways).
- description of analytical methods that may have been applied to measure the potential importance of different model inputs as contributors to variation in risk estimates and the results.
- comparison of the results of exposure assessment and hazard characterisation against any available data that were not included in the model (eg validation of model predictions against independent epidemiological or experimental data).
- a discussion of risk assessment outputs presented in a separate section of the report. This section may include the views of the risk assessors on the feasibility and effectiveness of specific hazard control measures, and other suggestions on the practical use of the risk assessment. By separating such views from the actual risk characterisation, the science-based analyses are separate and explicit.
- an interpretative summary to explain the purpose of the work, how the assessment was conducted, the results and conclusions, and the importance of the conclusions in a way that the average food consumer can understand. Flow charts, scenario trees,

diagrams, and other means of graphically representing the process and the results will be used by the Authority to convey information.

3.5 Communication of outcomes

While Codex designates the risk managers as having the overall responsibility for ensuring the results of the risk assessment are communicated appropriately to other relevant parties, the Authority will utilise the Communication & Corporate Resources Branch to facilitate these interactions, as they have the skills and resources necessary to implement a comprehensive risk communication strategy.

For full transparency, the Authority will ensure that all its risk assessment reports are publicly available on the Authority's website, with both a technical report and an interpretive summary to present the outcomes in a logical, easy to understand manner.

4. How the Authority will use risk assessment outcomes

Codex has developed guideline documents to provide guidance for food regulators in incorporating risk assessment findings as the basis for risk management decision making (Codex, 2007a).

4.1 The development of food safety standards

Under the NSW *Food 2003*, the Authority is required to underpin any new food safety regulatory measures with risk assessment. This aligns with the international approach to establishing food safety control measures where quantitative risk assessments are undertaken for specific hazards in the food supply, with the intention that the outputs of these risk assessments will be used in the development of food safety measures at the national level.

The Authority will use risk assessment to underpin the development of any new food safety standards, and also to justify the continuation of existing standards by:

- setting priorities amongst different food safety problems (eg risk ranking).
- addressing a specific public health food safety problem (eg *Salmonella* in poultry).
- justifying or evaluating a new or alternative measure, technology, or audit system.

4.2 Responding to urgent incidents

In cases of urgent issues requiring a rapid response, the ability to undertake a risk assessment may be limited and risk management decisions may have to be made on the basis of very limited scientific information to minimise the immediate risk. For issues impacting nationally, under the *National Food Incident Response Protocol* FSANZ is nominated as the risk assessor and the Authority will assist by providing data and other resources as appropriate.

The Authority is aware of the possible conflict of interest between the desired timeframe for results to be available versus the time needed to properly conduct a risk assessment. One option for supporting immediate, interim actions is the construction of interim food safety assessments which may contain some elements of a risk assessment, most notably an exposure assessment. The Authority considers that effective risk management decisions can still be made when only some of the components of risk assessment are available.

4.3 Monitoring control measures

The Authority may use risk assessment outputs to help set survey priorities. During the development of risk assessment work, there are inevitably areas where a lack of information exists to fully enable a quantitative risk assessment to be undertaken. For these, surveys may be prioritised to generate the data to fill these data gaps for future updates of the risk assessment.

Risk assessment outputs may also help identify any changes or emerging hazards from food commodities. The hazard characterisation should indicate the range of adverse health effects that may result from a particular hazard / food exposure pathway. This may facilitate survey design to effectively verify the findings of the risk assessment and substantiate to what degree the emergence of such hazards affects the NSW food supply chain.

5. Reviewing and updating risk assessments

5.1 Peer review

Codex recommends that risk assessments should be peer reviewed. Such reviews should be multidisciplinary and should be planned when initially commissioning the risk assessment. Different types of peer review may include:

- review by Authority staff.
- review by persons outside the Authority
- review by an advisory or scientific committee

Codex recommends that analytical aspects of any risk assessment should be peer reviewed by independent risk assessment experts, while other scientific inputs should be peer reviewed by experts in relevant fields. There is particularly important where outcomes may be sensitive or contentious, but it is also valuable that the validity of any assumptions included in the risk assessment are reviewed by individuals with different perspectives and expertise.

While it is obviously preferable for any risk assessment work conducted by the Authority to be subject to external independent peer review, within Australia the relevant expertise is limited to only a handful of consultants, government or university organisations.

5.2 A system for updating risk assessment outcomes

The spectrum and prevalence of hazards in the food chain is constantly changing. Furthermore, better monitoring and surveillance in recent years has led to a better understanding of the critical importance of microbiological pathogens and chemical hazards.

Codex states that risk assessments may need re-evaluation as new relevant information becomes available (Codex, 1999), and that risk estimates should be reassessed over time by comparison with independent human illness data. New scientific data are constantly becoming available, but the value of incorporating more data must be weighed against whether it will significantly change the outcomes of the risk assessment.

The Authority will compare the risk assessment findings with the foodborne illness data trends emanating from NSW, and also the national trends identified through OzFoodNet, as well as issues raised through the *National Food Incident Response Protocol* by FSANZ. Comparison of the risk estimate from the output of the risk assessment to the estimates of human illness

associated with the corresponding foods can provide a reality check by gauging the reliability of the predicted estimate and an opportunity to reassess the risk estimate.

In 2008-09 the Authority conducted a comprehensive risk assessment of the food safety schemes covering dairy, meat, seafood, plant products, vulnerable persons and the draft egg food safety scheme (NSW Food Authority, 2009). This was done in response to the remake of the Food Regulation 2004, which is required to be remade every five years. In line with the requirements specified in the *Food Act 2003*, the Authority undertook the risk assessment work to underpin the food safety schemes contained in the updated Food Regulation.

While the food safety scheme risk assessment provides a solid basis moving forward, it is a large undertaking to conduct a risk assessment on all food safety schemes simultaneously. The Authority intends to review and update risk assessments in a rolling manner, with one or two food safety scheme risk assessments reviewed each year. In this way, each risk assessment will be reviewed and updated within the five year timeframe for the review of the Food Regulation.

Determination of the food safety schemes to be given priority for review will be dependent on significant developments/published literature and risk assessment data becoming available. This may include:

- significant outbreaks
- emerging pathogens
- novel causes or
- unknown risk of specific foods, or
- input from peer review

6. Conclusion

This risk assessment policy outlines how the Authority will use the principles of risk assessment to base its risk management measures on, including the development of new regulatory measures and responses to urgent issues.

In developing risk assessment work, the Authority will use previous peer reviewed work wherever possible, but may commission additional risk assessment work it considers necessary to fill data gaps that inevitably arise.

Risk assessment outcomes may be used to inform survey priorities, to fill data gaps and to inform the evaluation of existing regulatory and non-regulatory measures.

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Appendix 1 - Suggested elements to include in a microbiological risk profile

(adapted from Codex, 2007b)[1]

A risk profile should present, to the extent possible, information on the following.

1. Hazard/food commodity combination(s) of concern:

- hazard(s) of concern
- description of the food or food product and/or condition of its use with which problems (foodborne illness, trade restrictions) due to this hazard have been associated
- occurrence of the hazard in the food chain.

2. Description of the public health problem:

- description of the hazard including key attributes that are the focus of its public health impact (eg virulence characteristics, thermal resistance, antimicrobial resistance);
- characteristics of the disease, including;
    - susceptible populations
    - annual incidence rate in humans including, if possible, any differences between age and sex
    - outcome of exposure
    - severity of clinical manifestations (eg case-fatality rate, rate of hospitalisation)
    - nature and frequency of long-term complications
    - availability and nature of treatment
    - percentage of annual cases attributable to foodborne transmission.
- epidemiology of foodborne disease
    - aetiology of foodborne diseases
    - characteristics of the foods implicated
    - food use and handling that influences transmission of the hazard
    - frequency and characteristics of sporadic foodborne cases
    - epidemiological data from outbreak investigations
- regional, seasonal, and ethnic differences in the incidence of foodborne illness due to the hazard
- economic impact or burden of the disease if readily available
    - medical, hospital costs
    - working days lost due to illness, etc

[1] Although the Codex document is specific to Microbiological risk profile, most of these elements are also applicable to risk profiles for non microbiological hazards, eg chemical and physical hazards

3. Food production, processing, distribution and consumption:
    - characteristics of the commodity that are involved and that may impact on risk management
    - description of the farm to table continuum (i.e., primary production, processing, transport, storage, consumer handling practices) including factors which may impact the safety of the commodity
    - what is currently known about the risk, how it arises with respect to the commodity's production, processing, transport and consumer handling practices, and who it affects
    - summary of the extent and effectiveness of current risk management practices including food safety production/processing control measures, educational programs, and public health intervention programs (eg vaccines)
    - identification of additional risk mitigation strategies that could be used to control the hazard
4. Other risk profile elements:
    - public perceptions of the problem and the risk
    - potential public health and economic consequences of establishing risk management measures
5. Risk assessment needs and questions for the risk assessors:
    - initial assessments of the need and benefits to be gained from requesting a risk assessment, and the feasibility that such an assessment could be accomplished within the required time frame
    - if a risk assessment is identified as being needed, recommended questions that should be posed to the risk assessor
6. Available information and major knowledge gaps provide, to the extent possible, information on the following:
    - existing risk management measure on the hazard/commodity combination(s) including, if possible
    - other relevant scientific knowledge and data that would facilitate risk management activities including, if warranted, the conduct of an risk assessment
    - existing Codex Codes of Hygienic Practice, international and/or national governmental and/or industry codes of hygienic practice and related information (eg microbiological criteria) that could be considered in developing risk management measures
    - sources of information and scientific expertise that could be used in developing risk management guidance documentation
    - areas where major absences of information exist that could hamper risk management activities including, if warranted, the conduct of an risk assessment.

Appendix 2 – Risk assessment tools used by the Authority

@RISK (Palisade Corporation) - is a risk analysis and simulation add-in for Microsoft® Excel. This program allows users to include distributions for input values (rather than just fixed values) and utilises either Monte Carlo or Latin Hypercube simulation to model the distribution of the outcome values. A large number of iterations can be run to allow the user to see the variety of possible outcomes from the inputs. The program can also undertake a sensitivity analysis to illustrate which input values most significantly influence the output. This is particularly useful for assessing the sensitivity of the risk assessment outcomes to any assumptions that have been made during the process. This software will be used for quantitative risk assessments to provide a risk estimate and uncertainty values.

Business sector food safety risk classification tool (Department of Health and Ageing) – is a set of decision trees developed to provide guidance on the allocation of Australian food businesses into categories based on their likelihood of contributing to foodborne disease and the potential magnitude of that contribution. The framework is designed to be science-based and transparent and applicable to primary production and manufacturing food businesses. The decision trees considers relevant biological, chemical and physical hazards associated with particular foods and processes; and reflects the inherent risks in the product/process, the potential of controlling the risks and a measure of their association with past foodborne illness outbreak information. While the Risk classification tool is not intended to be a substitute for food safety risk assessment, it can be useful as an initial tool for a qualitative risk assessment or risk profile

Risk ranger (Ross & Sumner, 2002) – is a simple, spreadsheet-based tool which is based on the established principles of food safety risk assessment, ie the combination of probability of exposure to a foodborne hazard, the magnitude of hazard in a food when present, and the probability and severity of outcomes that might arise from that level and frequency of exposure. The tool requires the user to select from qualitative statements and/or to provide quantitative data concerning factors that that will affect the food safety risk to a specific population, arising from a specific food product and specific hazard, during the steps from harvest to consumption. The spreadsheet converts the qualitative inputs into numerical values and combines them with the quantitative inputs in a series of mathematical and logical steps using standard spreadsheet functions. Those calculations are used to generate indices of the public health risk. While this tool does provide a simplified estimation of risk, without considering the variability and uncertainty in the inputs and outputs of the model as with the use of @RISK, offers a quick and simple means of comparing foodborne risks from diverse food products, and can rank and prioritise risks from diverse sources. It can be used to screen foodborne risks and identify those requiring more rigorous assessment. It can also help structure problem solving and focus attention on those factors in food production, processing, distribution and meal preparation that most affect food safety risk and may be the most appropriate targets for risk management strategies.

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