Review of Provisions in the Australia New Zealand Food Standards Code as they relate to Imported Seafood

March 2009

PURPOSE

This review of provisions in the *Australia New Zealand Food Standards Code* (the Code) relevant to imported seafood has been prepared by Food Standards Australia New Zealand (FSANZ) in response to the Election 2007 Policy Document, *Labor's Plan for Sustainable Fisheries – Seafood Safety Plan* which proposed to review the:

- provisions of the Code relating to seafood to ensure they adequately address the known risks; and
- existing testing protocols for seafood imports and consider any measures necessary to improve the food safety standards of imported seafood products.

AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE REQUIREMENTS PERTAINING TO SEAFOOD

Requirements in the Code apply equally to domestically produced and imported seafood. Code standards applicable to seafood are listed in Table 1 (see **Attachment 1**). In summary, the Code impacts on seafood in a number of ways:

- Provisions exist that limit residues that can be present in seafood from the use of agricultural and veterinary chemicals;
- The contaminants standard sets maximum levels for certain potential chemical contaminants;
- There are a number of microbiological limits for known human pathogens and other microorganisms that are indicators for human pathogens;
- The food additives standard provides permissions to use certain additives in seafood. For some permissions, maximum levels are prescribed;
- There are labelling requirements that apply to all foods, as well as the requirement to label seafood when used as an ingredient in a food.

The Code also includes a primary production and processing standard for seafood, which applies to seafood businesses, including seafood importers and seafood handlers. This standard requires management of different steps in the production and processing of seafood, and has more stringent requirements for high risk seafood products (bivalve molluscs).

AN ASSESSMENT OF THE FOOD SAFETY RISKS ASSOCIATED WITH SEAFOOD

Managing Risks Associated with Imported Food

Under the FSANZ Act, FSANZ is obliged to 'develop assessment policies in relation to food imported into Australia'. In practice, FSANZ provides advice to AQIS on the level of public health risk posed by specific imported foods while AQIS has operational responsibility for inspection and sampling of imported food. In addition to the role of AQIS at the border in relation to imported foods, State and Territory food enforcement agencies are responsible for enforcing the requirements of the Code for all food available for sale within their jurisdiction, including imported food.

The regulation of imported food at the border, with respect to food standards, occurs under the IFIS. The respective roles and responsibilities of FSANZ and AQIS under the IFIS are embodied in an MoU between the two agencies. The current MoU requires FSANZ to provide risk assessment advice in relation to high risk foods (i.e. Risk categorised food) and for AQIS to determine enforcement priorities for other aspects of the Code (i.e. low risk foods in the Random Surveillance category). Further information on the risk assessment and risk management approaches for each of the two categories follows.

> ***Risk categorised food:*** Food is risk categorised by FSANZ if it has the potential to pose a high or medium risk to public health. Risk categorised foods are inspected and tested against a pre-determined list of potential hazards, including mainly microbial and chemical hazards. Based on a risk assessment process, FSANZ provides advice to AQIS on which foods should be included in the risk category and the specific hazards of public health significance for these foods. The current risk category is available on the AQIS website at http://www.daffa.gov.au/__data/assets/pdf_file/0003/384402/Imported_Food_Notice_09_07.pdf
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> ***Random Surveillance category***: Foods in this category generally pose a low risk to public health and safety. The purpose of this category is to provide for monitoring of imported foods for compliance with the Code at a low inspection frequency. The current random surveillance category is available at http://www.daffa.gov.au/__data/assets/pdf_file/0008/476342/imported-food-notice-11-07.pdf

FSANZ, as part of its obligations under the Imported Food Inspection Scheme (IFIS), provides regular advice to the Australian Quarantine and Inspection Service (AQIS) on the level of public health risk posed by specific foods, including some seafood products, when specific issues are raised about the safety of these foods. In the case of seafood, FSANZ has determined that particular imported seafood (fish, molluscs, crustacea and marinara mix) pose a medium/high food safety risk due to potential microbiological, chemical and toxin contamination. Table 2 provides further details of these food safety risks.

Table 2

Food category	Requirement/analyte/hazard
Fish	Histamine, *L. monocytogenes*
Molluscs	*E. coli*, standard plate count, paralytic shellfish poison, domoic acid, *L. monocytogenes*
Crustacea	Coagulase positive staphylococci, *Salmonella*, standard plate count, *Vibrio cholerae*
Marinara mix	Coagulase positive staphylococci, *E. coli*, *Salmonella*, paralytic shellfish poison, domoic acid

2007 Review

Testing requirements for high risk imported seafood were most recently reviewed by FSANZ in 2007 under newly developed 'risk list criteria' which formalise the risk assessment methodology used in previous reviews. The criteria were developed for assessing whether a particular food/hazard pair is a medium/high risk for imported food testing purposes. The scientific literature and imported food test data were used to inform whether particular imported seafoods have caused illness in humans, whether seafoods are contaminated with microbiological or chemical hazards, whether these hazards cause illness in particular parts of the population (e.g. the whole population of susceptible groups) and whether post-import treatments would reduce the risk of these hazards to consumers.

The review showed that:

- for imported tuna and mackerel, there was evidence that histamine poisoning had occurred, and that post-import treatments would not reduce the risk to consumers.
- processed ready-to-eat finfish had been associated with illness caused by *Listeria monocytogenes*, particularly in consumers more susceptible to food foodborne illness.
- imported cooked crustacea (e.g. prawns and crayfish) had been linked to illness caused by *Salmonella*. Illness caused by coagulase positive staphylococci was not apparent but was thought to be possible. There was historical evidence of contamination of crustacea with these hazards, and not all post-import treatments would sufficiently reduce the risk.
- chilled or frozen imported bivalve molluscs (e.g. oysters and mussels) were found to be associated with illness caused by the toxins paralytic shellfish poison and domoic acid. Post-import treatments would not reduce the risk of toxin contamination. In addition to possible contamination with these hazards, processed ready-to-eat bivalve molluscs had been linked to illness caused by *L. monocytogenes*, and not all treatments after importation could be relied upon to mitigate the risk.

Based on FSANZ's assessment that these hazards pose a medium or high risk to consumers, it is expected that AQIS will retain tests for these products. *E.* coli and standard plate count tests were not assessed during the 2007 review. FSANZ is conducting a separate process to review standards setting options for *E. coli*. Setting regulatory measures for *E. coli* is challenging because some *E. coli* strains cause illness in humans, while others do not and have been used traditionally as indicators of food hygiene. FSANZ expects to complete this

work in 2009, and will then begin work on the efficacy of standards for indicators (e.g. standard plate count). The outcomes of this work will have implications for microbiological standards in the Code, as well as corresponding tests applied by AQIS at the border.

In response to further concerns raised by some stakeholder groups about the safety of imported seafood, AQIS conducted a survey of antimicrobial and pesticide residues in imported seafood between April 2006 and March 2007. This survey revealed that some seafood products entering Australia contained low-level residues of antimicrobial compounds that did not comply with Standard 1.4.2 of the Code.

FSANZ undertook a risk assessment of the data flowing from the AQIS survey to compare the estimated dietary exposures with the established reference health standard (Acceptable Daily Intake) for each chemical compound. In conducting this risk assessment, FSANZ focussed specifically on the thirteen compounds detected in the survey, which represented at least six antimicrobial chemical groups – the sulphonamides, fluoroquinolones, phenicols, tetracyclines, β-lactams, and triphenyl methane dyes (malachite green). The risk assessment did not identify any major safety concerns associated with the residues detected. However, AQIS added several antibiotics (penicillin, fluoroquinolones and quinolones) to its testing regime for imported seafood under the Random Surveillance category given some evidence of non-compliance. AQIS has recently removed testing of penicillin and quinolones based on favourable compliance history.

2005 Nationally Coordinated Survey

In 2005, a nationally coordinated survey was conducted by Australian food enforcement agencies on chemical residues in aquacultured fish, in which 60 samples of local and imported aquacultured finfish were sampled from across Australia. Samples were analysed for a range of over 50 substances and their metabolites including nitrofurans, chloramphenicol, sulphonamides, tetracyclines, malachite green, penicillins, macrolides, trimethoprim, quinolones and polychlorinated biphenyls. Overall, the results were favourable, with only malachite green and/or its metabolite, leucomalachite green, being detected. Malachite green and/or leucomalachite green were detected in ten samples; three fish grown in Australia and seven Basa fish samples imported from Vietnam. The residues were at low levels, i.e. all less than 0.1 mg/kg. FSANZ subsequently undertook a risk assessment of these results and concluded that malachite green residues in aquaculture fish would not pose a public health risk at the reported levels. Following the survey, AQIS instituted testing of malachite green in aquaculture fish under the Random Surveillance category.

2004 Review

In 2004, FSANZ conducted a comprehensive risk assessment on seafood, *A Risk Ranking of Seafood in Australia*[1], to provide a consolidation of current scientific information for the development of the primary production and processing standard for seafood. The assessment provided a relative risk ranking of imported and domestically produced seafood.

[1] The Risk Ranking is attached to FSANZ's Final Assessment Report, available at http://www.foodstandards.gov.au/_srcfiles/P265_Seafood_PPPS_FAR.doc.

The risk assessment took into account the chemical and biological food safety hazards potentially present, and assigned each commodity or group of commodities to a broad relative risk category: low, medium or high. The assessment considered the potential introduction of veterinary drugs, chemical contaminants and microorganisms by various routes, and any potential changes in the levels of these hazards over time. The ranking brought together the available scientific and technical information on food safety hazards in seafood and identified seafood commodities of higher priority for the development of risk management strategies in the context of the primary production and processing standard for seafood.

Generally, there was found to be a high degree of safety associated with the consumption of seafood in Australia. Under current risk management practices – both voluntary and mandatory – public health risks were found to be relatively low for the majority of seafood products. However, two seafood groups were found to pose a higher relative risk:

- oysters and bivalve molluscs (except when the consumed product is only the adductor muscle, for example, roe-off scallops) harvested from growing environments likely to be exposed to faecal contamination and/or not under a shellfish safety management scheme; and
- ready-to-eat smoked finfish (and other ready-to-eat cold smoked seafood products), when eaten by population sub-groups susceptible to Listeriosis.

As a result of these findings, specific risk management measures[2] for bivalve molluscs were developed to manage the risk. However, it was considered that existing risk management measures for smoked finfish (including microbiological standards and education materials for susceptible populations) were sufficient to manage the risk without the addition of new measures.

AQIS reviews food in the Random Surveillance category and tests at a frequency of 5%. As AQIS has operational responsibility for inspection and sampling of these imported foods, it determines the appropriate risk management regime that would be applied. Further details are outlined in Table 3.

Table 3

Food category	Requirement/analyte/hazard
Fish	Histamine (other than tuna and mackerel), malachite green, penicillin, fluoroquinolones
Molluscs	No analytical tests
Crustacea	Sulphur dioxide, nitrofurans, fluoroquinolones, quinolones
Seafood extracts	Pesticide screen[3]
Caviar	Malachite green, penicillin, fluoroquinolones

[2] A seafood business that engages in the primary production or processing of, or manufacturing activities concerning, bivalve molluscs must implement a documented food safety management system that effectively controls the hazards.

[3] The pesticide screen comprises tests for 49 agricultural chemicals. The screen includes a combination of chemicals for which there are MRLs in the Code, and chemicals without an MRL (and therefore no detectable residue is permitted).

ONGOING ACTIVITIES TO IDENTIFY RISKS AND INITIATE COMMENSURATE RISK ASSESSMENT AND RISK MANAGEMENT RESPONSES

There are a number of mechanisms through which FSANZ monitors developments domestically and internationally for early warning signals on potential problems with imported food.

Arrangements with International Food Authorities

FSANZ has established Memoranda of Understanding (MoUs) with regulatory authorities in several countries. Although these MoUs vary in their specific purpose, they aim to encourage cooperation on food standards development, risk assessment, improved communication and to allow sharing of non-public food safety information. FSANZ currently has MoUs with:

- Canadian Food Inspection Agency
- Health Canada
- Chinese Ministry of Science and Technology
- Chinese State Food and Drug Administration
- New Zealand Environmental Risk Management Authority
- New Zealand Food Safety Authority
- United Kingdom Food Standards Agency

FSANZ and the United States Food and Drug Administration (US FDA) have also recently signed a Confidentiality Commitment which will facilitate sharing of non-public food safety information. The Commitment allows the agencies to share information on emerging food incidents and food recalls, and permits FSANZ to share confidential commercial information for enforcement or recall purposes.

International Inter-Governmental Organisations and Forums

FSANZ is an active participant in the work of the Codex Alimentarius Commission, which is the international food standards body established under the Food and Agricultural Organisation (FAO) and the World Health Organisation (WHO). FSANZ officers attend meetings of relevant Codex committees and also participate on a number of the expert groups established under the FAO/WHO that assess risks associated with pesticides, food additives and contaminants and microbiological hazards. These networks are an important source of information to FSANZ on emerged and emerging issues.

Information regarding the safety of imported food may be brought to the attention of FSANZ or AQIS through INFOSAN[4], regular monitoring (for example, through the Monitoring of Emerging Issues newsletter[5]) or through intelligence supplied from jurisdictions or other government agencies.

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[4] INFOSAN, the International Food Safety Authorities Network, provides a mechanism for the exchange of information on both routine and emerging food safety issues. As of October 2006, 151 countries are members of the INFOSAN network. INFOSAN is co-ordinated by the World Health Organization.

[5] The Monitoring of Emerging Issues newsletter, prepared by FSANZ, includes international and national issues of food safety concern and international rapid alert system briefs for food and feed.

FSANZ also actively participates in an International Food Chemical Safety Liaison Group which is a forum of international food regulators that discusses chemical food safety issues of mutual interest within a confidential framework.

Imported Food Surveys

Surveys on imported food are carried out by AQIS. The design and scope of these surveys are performed in consultation with FSANZ and the results of the surveys are provided to FSANZ to inform the risk analysis process. Analyses of the results by FSANZ, for example in the form of a risk assessment, are provided to AQIS upon request.

Consultation with Stakeholders

In addition to exchanging information with national and international government agencies, FSANZ liaises closely with industry and consumer groups, as well as the Imported Food Consultative Committee (IFCC). The IFCC is the principal route by which AQIS and FSANZ consult with the food industry on matters related to the importation of food under the *Imported Food Control Act 1992.*

Changes in Quarantine Orders

The importation of some products is subject to certain quarantine conditions, outlined in the AQIS Import Conditions database (ICON[6]). Australia's quarantine policy is based on the assessment and management of pest and disease risk to human, animal and plant health and the environment.

CONCLUSION

There are a number of standards in the Code that relate to seafood. These standards apply to both domestically produced and imported seafood and have been developed following rigorous scientific analysis (including peer review) and an open and transparent consultation process. In FSANZ's view, the standards in the Code are scientifically robust and provide an appropriate level of protection for Australian consumers of seafood.

A comprehensive risk assessment on seafood was conducted in 2004. The risk assessment concluded that there was a high level of safety associated with seafood consumed in Australia, although bivalve molluscs and smoked finfish were identified as two product groups with a higher than normal risk profile. Specific risk management measures for bivalve molluscs were developed; however, it was considered that existing risk management measures for smoked finfish were sufficient to manage the risk without the addition of new measures.

In the period since 2004 until the present, there have been a number of risk assessments conducted in respect of specific imported seafood products, using data generated through monitoring and surveillance activities. While some of these data identified non-compliance with some standards, an assessment of the risks confirmed there were no public health and safety issues.

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[6] Information on the Import Conditions database can be found at: http://www.aqis.gov.au/icon32/asp/homecontent.asp

FSANZ conducts regular reviews of food products against the standards in the Code and has determined that particular imported seafood (fish, molluscs, crustacea and marinara mix) pose a medium/high food safety risk due to potential microbiological, chemical and toxin contamination. The most recent of these reviews (conducted in 2007) confirmed most of the existing tests for high risk seafood, due to evidence of contamination with particular hazards, and evidence in most cases that these hazards have caused illness in humans. These tests include histamine in tuna and mackerel; *L. monocytogenes* in processed finfish; microbiological hazards and toxins in marinara mix; microbiological hazards in cooked crustacea; *Vibrio cholerae* in shrimps and prawns; and microbiological hazards and toxins in bivalve molluscs.

FSANZ has a number of intelligence gathering and feedback mechanisms in place, both domestically and internationally, that will continue to be used to monitor potential safety risks associated with imported seafood and act as a trigger for food safety risk assessments and, as necessary, changes to risk management approaches.

BACKGROUND

Development and Implementation of Food Standards in Australia

FSANZ is an independent statutory agency established by the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act). FSANZ sets food standards in the Code for the two countries and works within an integrated food regulatory system involving the governments of Australia and New Zealand.

FSANZ's primary objective is to develop standards that ensure a safe food supply and well-informed consumers. Food standards developed by FSANZ cover the content and labelling of food sold in Australia and New Zealand. FSANZ also develops Australia-only food standards that address food safety issues, including requirements for primary production and processing, and maximum residue limits for agricultural and veterinary drug residues.

To sell food in Australia and New Zealand, food companies and retailers must comply with food standards in the Code. Food standards are legal requirements and non-compliance can attract penalties. Enforcement of the Code is the responsibility of the State, Territory and New Zealand food enforcement agencies, and, in respect of imported food, AQIS.

The development of, or amendment to, a food standard is either by an application lodged by an outside body (usually a food business) or a proposal prepared by FSANZ. The standard development process involves an evaluation of the risk to public health of the proposed change to the Code and the impact of the regulatory measures on the food industry and international trading obligations. FSANZ then drafts a standard for public comment. There may be one or more periods of public consultation for each standard.

Once a draft standard is approved by the FSANZ Board, the decision is notified to the Australia and New Food Regulation Zealand Ministerial Council (Ministerial Council) and, if the Ministerial Council does not request a review of FSANZ's decision within 60 days, FSANZ gazettes the standard. The standard is adopted by reference into State and Territory Food Acts and the *Imported Food Control Act 1992*.

FSANZ has responsibility for developing and maintaining risk analysis methodology for imported food, including 'risk list criteria' for evaluating and reviewing food in the risk category. The criteria, formalised in 2007, are a decision making tool which draws on risk assessment principles and is used to assess whether an imported food/hazard combination poses a high or medium risk for the purposes of high frequency control at the border. The criteria take the form of a decision tree, and include a number of factors to be considered: whether a particular food is associated with foodborne illness; the likelihood of the hazard being in a particular imported food; the severity of illness associated with the hazard (including consideration of sub-populations that may be more susceptible); and whether there are appropriate hazard reduction strategies after import. They recognise existing standards, but also allow for measures to be applied solely to imported foods, where justified by evidence.

In developing amended advice on the Risk category, FSANZ consults with relevant stakeholders (e.g. domestic industry, importers, State, Territory and New Zealand Government enforcement agencies), who are given an opportunity to provide comment. Amended advice is notified to AQIS in writing. If AQIS makes an amendment to the Risk category, it notifies FSANZ and communicates the change to its stakeholders in an Imported Food Notice.

In some cases, FSANZ or other appropriate agencies may need to undertake a more formal risk assessment in relation to an imported food, usually when a supporting food standard (and therefore a risk assessment) does not exist. When conducting risk assessments, FSANZ uses the internationally accepted risk assessment methodology developed by the Codex Alimentarius Commission. FSANZ has a number of dedicated risk assessment sections in the areas of chemistry, microbiology and public health nutrition, and expert staff qualified in toxicology, nutrition, food technology, microbiology, molecular genetics, dietary exposure assessment and public health nutrition. FSANZ seeks extensive peer review nationally and internationally on its risk assessments, and amends its risk assessment advice in the light of any new evidence.

AQIS contributes to the categorisation process by providing information on test results, manufacturers, the nature of the products and the source of the products. FSANZ also provides information on the intent of the food standards in the Code, if requested.

FSANZ can be prompted to provide advice to AQIS about Risk category foods by the emergence of new food safety issues, including through international intelligence gathering, following changes to quarantine arrangements that permit the importation of new foods, or following reviews of the imported food risk category. FSANZ works with Biosecurity Australia at the time that Import Risk Analyses are undertaken in order to determine whether human food safety issues need to be considered. FSANZ also works with the Department of Health and Ageing during this process to ensure that human food safety and human quarantine issues are considered together.

Attachment 1

Table 1

Standard	Food category	Requirement/analyte/hazard
Labelling	Seafood	Description of the food to indicate its true nature; lot identification; name and address of supplier; declaration that seafood is present when used as an ingredient, food additive or processing aid; directions for use and storage; date marking; nutrition information panel (packaged seafood); country of origin labelling; editorial note pertaining to fish marketing names in Australia and New Zealand.
Food additives (maximum levels apply to some permissions)	Unprocessed frozen fish	Ascorbic acid and sodium, calcium and potassium ascorbates; erythorbic acid and sodium erythorbate; sodium, potassium and calcium phosphates; pyrophosphates; triphosphates; polyphosphates
	Unprocessed uncooked crustacea	Sulphur dioxide and sodium and potassium sulphites; ascorbic acid and sodium, calcium and potassium ascorbates; erythorbic acid and sodium erythorbate; citric acid and sodium, potassium, calcium and ammonium citrates; sodium carbonates; magnesium carbonates; 4-hexylresorcinol
	Processed cooked crustacea	Sulphur dioxide and sodium and potassium sulphites
	Processed, semi-preserved and fully preserved roe	Amaranth
	Semi-preserved fish and fish products	Annatto extracts; sorbic acid and sodium, potassium and calcium sorbates; benzoic acid and sodium, potassium and calcium benzoates
	Fully preserved fish including canned fish products	Sulphur dioxide and sodium and potassium sulphites; calcium disodium EDTA
	Fully preserved canned abalone	Sulphur dioxide and sodium and potassium sulphites
Chemical hazards and composition (maximum levels apply)	All seafood	Tin (if canned), acrylonitrile, vinyl chloride
	Fish	Inorganic arsenic, lead, mercury, polychlorinated biphenyls, histamine (tuna and mackerel)
	Molluscs	Mercury, cadmium, lead, amnesic shellfish poisons (domoic acid), diarrhetic shellfish poisons, neurotoxic shellfish poisons, paralytic shellfish poisons
	Crustacea	Inorganic arsenic, mercury

Cont'd

Standard	Food category	Requirement/analyte/hazard
Maximum residue limits for agricultural and veterinary chemicals[7]	Fish	Benzocaine, isoeugenol, oxytetracycline, aldrin, dieldrin, hexachlorocyclohexane, chlordane, DDT, hexachlorobenzene
	Molluscs, crustacea	Aldrin, dieldrin, hexachlorocyclohexane, chlordane, DDT, hexachlorobenzene, heptachlor, lindane
Microbiological hazards	Processed fish	*Listeria monocytogenes*
	Molluscs	*Eschericha coli*, *L. monocytogenes*
	Crustacea	Coagulase positive staphylococci, *Salmonella*, standard plate count
Primary production, processing and Food Safety Standards.		The Primary Production Standards and the Food Safety Standards provide through chain management of food safety in the seafood sector, including for all primary producers, retailers, manufacturing businesses, distributors, importers and food service businesses that handle seafood. A seafood business must identify potential seafood safety hazards and implement controls that are commensurate with the risk. Additionally, primary producers and processors of certain bivalve molluscs are required to implement a food safety management system. This particular requirement also extends to manufacturing activities relating to bivalve molluscs. For primary producers and processors of bivalve molluscs, the food safety management system incorporates conditions on the areas from which the product may be harvested or harvested for depuration or relaying, along with conditions on the water used for wet storage. The Food Safety Standards specify process control requirements at each step of the food handling process and premises, equipment and vehicles used by food businesses.

[7] If a maximum residue limit for an agricultural or veterinary chemical in a food is not listed in the Code there must be no detectable residues of that agricultural or veterinary chemical in that food.