Proposal P1017
Criteria for *Listeria monocytogenes* – Microbiological Limits for Foods

Major Procedure

Summary

FSANZ is assessing a proposal to revise Standard 1.6.1 of the Food Standards Code to amend the criteria for *Listeria monocytogenes* limits in ready-to-eat (RTE) foods. This forms the first part of a broader review of the microbiological limits and guidelines contained in the Code and various user guides and guidelines available on the FSANZ website.

At this stage, three options have been proposed:

Option 1 – Amend the limits for *Listeria monocytogenes* in Standard 1.6.1

Option 2 – No limits in Standard 1.6.1 and establish reference criteria

Option 3 – Status quo

NSW supports Option 1 to amend the limits for *L. monocytogenes* in Standard 1.6.1 to align with the approach taken by the Codex Alimentarius Commission, whereby an allowable level of up to 100 cfu/g may be present in RTE foods that cannot support the growth of the organism.

Specific Issues

The move towards allowing the presence of some *L. monocytogenes* cells in certain foods has already taken place in several countries, with the European Union (EU, 2005), Canada (Health Canada, 2010) and the Codex Alimentarius Commission (CAC/GL, 2007) all allowing up to 100 cfu/g in foods that will not support the growth of the organism. In addition, Germany, the Netherlands and Denmark classify foods into categories, with limits set for each category. For example, in foods where it can be demonstrated that *Listeria* cannot grow, some samples (2 out of 5) are allowed to contain between 10 and 100 cfu/g, but no sample can exceed 100 cfu/g (Meat Industry Services, 2005).

The Authority contends that there is enough evidence to support an allowable level of *L. monocytogenes* in foods. The organism has been the subject of large amounts of research and risk assessment work by food regulators all over the world. This work has shown that, while the infective dose for *L. monocytogenes* has proven difficult to accurately define due to individual susceptibility, it has become increasingly apparent that both the invasive and non-invasive forms of listeriosis require high numbers of the organism to infect even highly susceptible individuals. The Authority believes that an approach to allow levels of *L. monocytogenes* up to 100 cfu/g in foods where it will not grow will provide the correct balance between the protection of public health and achievable limits for the food industry to consistently comply with.

Prevalence of Listeria monocytogenes in foods

The NSW Food Authority routine survey testing data from 2003 to mid 2012 shows that *L. monocytogenes* was present in 62/4211 (1.5%) of RTE food samples tested. The Authority has enumerated the organism in more recent samples, with the range of counts shown in Table 1.

Table 1. Enumeration of *L. monocytogenes* in positive samples for RTE foods

Food category	Number of samples	% samples *L. monocytogenes* detected	*L. monocytogenes* counts on enumerated samples (cfu/g)		
			<10	10-100	100-1000
Beverage	3	—	—	—	—
Desserts	51	—	—	—	—
Cheese	375	2 (0.53%)	—	—	—
Cream	9	—	—	—	—
Custard	13	1 (7.69%)	—	—	—
Dip/Spread/Pate	100	—	—	—	—
Eggs	2	—	—	—	—
Fresh Cut Fruit	90	—	—	—	—
Fresh Cut Vegetables	203	—	—	—	—
Fresh Produce	78	—	—	—	—
Herbs/Spices	4	—	—	—	—
Ice Cream/Gelato	61	4 (6.56%)	1	—	—
Juice	31	—	—	—	—
Juice, unpasteurised	41	—	—	—	—
Kashta	1	—	—	—	—
Meat, RTE	707	22 (3.11%)	3	1	—
Milk, pasteurised	38	—	—	—	—
Milk, unpasteurised	334	—	—	—	—
Mixed Dish	23	—	—	—	—
Noodles	54	—	—	—	—
Pasta / Rice	6	—	—	—	—
Poultry, RTE	334	6 (1.80%)	1	1	—
Puree	91	—	—	—	—
Quiche/Pastie/Savoury Roll/Savoury Pie	5	—	—	—	—
Salad	192	8 (4.17%)	1	1	—
Sandwich/Wrap/Roll	135	4 (2.96%)	—	—	—
Sauces	19	—	—	—	—
Seafood, RTE	213	4 (1.88%)	—	—	3
Seed Sprouts	211	—	—	—	—
Shellfish	28	—	—	—	—
Sushi	561	9 (1.60%)	—	—	—
Tofu	76	—	—	—	—
UCFM	47	2 (4.26%)	1	1	
Vegetables in oil/bottled/canned	48	—	—	—	—
Yoghurt	27	—	—	—	—
TOTAL	**4211**	**62 (1.47%)**	**7**	**4**	**3**

In addition to routine surveys, the Authority has undertaken investigations of suspected food poisoning outbreaks due to *L. monocytogenes*. The results of two major investigations in 2009 are shown in Table 2. The counts on food samples taken as part of foodborne illness investigations tended to be much higher than found in routine samples.

Table 2. Samples taken as part of foodborne illness investigations

Food category	Number of Samples	% samples *L. monocytogenes* detected	*L. monocytogenes* counts on enumerated samples (cfu/g)					
			<10	10-100	100-1000	1000-10,000	10,000-100,000	>100,000
Diced chicken	32	14 (43.75%)	—	7	4	2	1	—
Salted chicken	14	14 (100.00%)	—	1	2	1	—	7

Prevalence data summarised by Ross et al (2009) also showed the vast majority of samples where *L. monocytogenes* was detected, 88-96% of samples were at levels than 100 cfu/g (Table 3).

Table 3. Levels of *L. monocytogenes* on contaminated processed meats

Contamination level (cfu/g)	Percentage (%) of samples in contamination levels range				
	≤ 10	10-100	100-1000	1000-10,000	≥ 10,000
FDA & USDA (2003) - retail	79.7%	8.6%	7.1%	2.3%	2.2%
Cumulative total		**88.3%**	**95.4%**	**97.8%**	**100.0%**
Gombas et al (2003) - retail	87.8%	2.4%	8.6%	1.2%	
Cumulative total		**90.2%**	**98.8%**	**100.0%**	
Health Department WA - production	88.7%	7.3%	1.7%	2.3	
Cumulative total		**96.0%**	**97.7%**	**100.0%**	

Adapted from (Ross, Rasmussen, Fazil, Paoli, & Sumner, 2009)

The risk assessment undertaken by the US (FDA & USDA, 2003) estimated that more than 96% of listeriosis cases are due to doses greater than 10^5 cfu/serving *L. monocytogenes* (see Table 4).

Table 4. Estimated dose per serving and incidence of foodborne listeriosis

L. monocytogenes in food at time of consumption (cfu/serving)	% servings annually	% listeriosis cases attributable
0.04 (detection level of 1 in 25 g)	96.37	0.02
0.1	1.90	<0.01
1	0.91	0.01
10	0.43	0.03
100	0.21	0.13
1,000	0.10	0.60
10,000	0.05	2.85
100,000	0.02	13.47
>1,000,000	0.01	82.89

Adapted from FDA/USDA (2003)

This is in contrast to the number of servings that may contain the organism at levels of 100 cfu/serving or less which were attributed to causing less than 0.2% of listeriosis cases. Given that the average number of notified cases of listeriosis in Australia each year is approximately 60-70 cases, then extrapolating the US findings would equate to food containing 100 cfu/serving being the cause of one case of listeriosis in Australia every 7 years.

According to FSANZ's own statistics on food recalls, approximately 50% of the recalls over the past 10 years due to microbiological contamination have been due to the presence of *L. monocytogenes*. The prevalence data shown in the above tables show that 80-90% of food contaminated by *L. monocytogenes* occurs at levels less than 100 cfu/g. With risk assessment data showing that this level is unlikely to result in cases of listeriosis, a change in Standard 1.6.1 may allow some flexibility for industry, minimising what may be costly and unnecessary recalls.

Probability of illness from L. monocytogenes

With *L. monocytogenes* likely to be present in 1-2% of RTE foods, this means that it may be consumed several times a year by many people in the population. However the number of reported cases in Australia each year is quite small, around 50-70 cases compared with the millions of serves of food consumed each year that may contain the organism.

The probability of contracting listeriosis was estimated by Buchanan et al (1997), who combined epidemiological and food survey data to calculate that a consumption level of 100 cfu/g (in a 50g serving) would result in a probability of 6.10×10^{-9} of acquiring listeriosis. The authors concluded "even with this conservative estimate, it is apparent that the probability that a high-risk individual will acquire symptomatic listeriosis is extremely low unless high levels of the pathogen are consumed". The authors also stated "focus for risk management decisions should be the prevention of the growth of this pathogen in food to high levels. This would have the greatest public health impact on a cost benefit basis".

In addition, the FAO/WHO (2004) found that in general, the levels of *L. monocytogenes* in the implicated food have exceeded 10^3 cfu/g and that a dose response could be calculated using the formula:

$$P = 1\text{-}e^{-r*N}$$

where *P* is the probability of illness; *N* is the ingested dose and *r* is the probability that a single cell causes illness – calculated to have a value of 5.85×10^{-12} for the susceptible population and 5.34×10^{-14} for the general healthy population.

These calculations tend to demonstrate why listeriosis is a relatively rare illness, even among the susceptible population, despite the organism being consumed frequently at low levels. Given this information, countries such as Canada and the EU have introduced risk-based management strategies and given a lower priority to products in which the organism cannot grow or, has a limited potential for growth whereby the levels do not exceed 100 cfu/g throughout the shelf life of the food.

Improvements in control measures

Since first coming to prominence as a foodborne pathogen in the mid 1980's, knowledge of *L. monocytogenes* and listeriosis has increased significantly. New controls are now being applied to food production and processing to minimise the

potential for contamination with *Listeria* to occur, and if contamination does occur, to minimise the amount of growth.

Some examples of improvements include:

- better and more targeted environmental monitoring of the organism in the food production environment – minimum requirements are in place for the dairy (*Australian Manual for Control of Listeria in the Dairy Industry*) and meat industries (*Listeria Management Program*)
- better targeting of *L. monocytogenes* with cleaning and sanitation programs
- better equipment design and control over cross contamination
- increased used of commercial additives such as lactate and diacetates to inhibit the growth of *L. monocytogenes*
- The application to use anti-*Listeria* bacteriophage
- Hold and release testing of finished product

Under Standard 1.6.1 any detection of the organism in these products would still be considered a breach of the Code.

Because *L. monocytogenes* occurs naturally in the environment, and can become endemic in the factory environment, it is inevitable that it will contaminate some food from time to time. It is unrealistic to expect that *L. monocytogenes* can be entirely eliminated from food, but it is important that the level of contamination is controlled and kept as low as possible.

There is potential for the current zero-tolerance approach to be counter-productive. Warriner & Namvar (2009) argue that by having zero tolerance it is a common practice for US processors to perform minimal environmental monitoring and end-product testing given that any positive sample would result in an automatic recall.

Definition for ready-to-eat foods

FSANZ welcomes information or comment on existing definitions for ready-to-eat and specific considerations that may need to be taken into account when applying criteria for *L. monocytogenes* to this category of foods

In NSW's submission to A1045, the Authority supported the inclusion of a definition of ready-to-eat in Standard 1.1.1, but noted there are currently definitions in both Standard 3.2.2 and 3.3.1 of the Code as follows:

- **3.2.2 - 'ready-to-eat food** means food that is ordinarily consumed in the same state as that in which it is sold and does not include nuts in the shell and whole, raw fruits and vegetables that are intended for hulling, peeling or washing by the consumer.'
- **3.3.1 -** '**ready to eat** in relation to food means food that is ready for consumption, but includes food that may be re-heated, portioned or garnished or food that undergoes similar finishing prior to service.'

In addition, there are other relevant definitions of ready-to-eat foods in use:

AQIS definition
RTE is defined as a product that is edible without additional preparation to achieve food safety and may receive additional preparation for palatability or aesthetic, epicurean, gastronomic or culinary purposes

Codex definition (CAC/GL, 2007)
Ready-to-eat food – Any food which is normally eaten in its raw state or any food handled, processed, mixed, cooked, or otherwise prepared into a form which is normally eaten without further listericidal steps.

Consideration may be given to creating one single definition of ready-to-eat that is applicable throughout the Code to avoid creating inconsistencies

FSANZ welcomes information or comment on whether adequate guidance or tools are available for industry or enforcement agencies to validate whether a food can support the growth of *L. monocytogenes* or not.

Assessing whether a product supports the growth of Listeria monocytogenes

One of the main difficulties in the implementation of an allowable level of *L. monocytogenes* is determining whether a product does, or does not, support the growth of the organism.

The Authority believes that the Code should follow the examples used by organisations that have already implemented such a limit. For example, under European Union regulations (EC 2073/2005), a RTE food or ingredient with a shelf life of less than 5 days is considered to be unable to support the growth of *L. monocytogenes*. A similar approach is also used by Health Canada who's policy states that this time period would not allow sufficient time, under reasonably foreseeable conditions of distribution, storage and use, for *L. monocytogenes* to grow to levels above 100 cfu/g by the end of the stated shelf-life (Health Canada, 2010).

It is up to a food business to demonstrate that their products do not support the growth of *L. monocytogenes* and the Authority believes that it should be up to each business to decide whether this is a commercial imperative for them to undertake this exercise. As stated by Codex, the demonstration that *L. monocytogenes* will not grow in a ready-to-eat food should take into account the measurement error of the quantification method. Therefore, for example, for practical purposes, a food in which growth of *L. monocytogenes* will not occur will not have an observable increase in *L. monocytogenes* levels greater than (on average) 0.5 log cfu/g[1] for at least the expected shelf life as labelled by the manufacturer under reasonably foreseeable conditions of distribution, storage and use, including a safety margin.

As also noted by Codex, "…if information is lacking to demonstrate that *L. monocytogenes* will not grow in a ready-to-eat food during its expected shelf life, the food should be treated as a ready-to-eat food in which growth of *L. monocytogenes* can occur …". Therefore the default position for regulators is likely to be that, unless the business has sufficient data to demonstrate that the product does not support the growth of *L. monocytogenes*, then the nil tolerance for *L. monocytogenes* would apply such that any detection would likely result in a recall.

The Authority suggests there would be value in developing some guidance material for industry to provide clarity on what information is likely to be considered satisfactory. Since Codex implemented these limits several years ago, there should be many opportunities for FSANZ to assess what materials are used by other countries to establish whether *L. monocytogenes* grows in a product or not.

[1] 0.5 log is two times the estimated standard deviation (i.e. 0.25 log) associated with the experimental enumeration using viable counting/plate counts.

It is the opinion of Codex that national governments should provide guidance on the specific protocols that should be employed to validate the studies demonstrating that growth of *L. monocytogenes* will not occur in a food during the expected shelf life. One option might be that an editorial note be included in the Standard that sets out the parameters for food that do not support the growth of *L. monocytogenes*.

Predictive microbiology as a tool

The NSW Food Authority has used the predictive microbiological model developed by Paw Dalgaard and colleagues at the Technical University of Denmark to assess the potential for growth of *L. monocytogenes* in foods. The Seafood Spoilage and Safety Predictor (SSSP), available as freeware from http://sssp.dtuaqua.dk/ also contains a very comprehensive model for the growth of *L. monocytogenes* containing up to 12 parameters. The model has been thoroughly validated for use in seafood and meat products ((Mejlholm et al., 2010).

The main restriction on using this model has been that, in many cases, the industry does not have the data on the parameters used in the model to adequately demonstrate one way or the other if the product supports the growth or not. In addition, for food products that are near the growth/no growth boundary for *Listeria* any variability in the process (eg water activity, nitrite, pH of the finished product) could have a profound effect on whether the organism could grow or not. The degree of process variability will need to be assessed in determining whether a product supports the growth of *L. monocytogenes*.

As stated previously, to this point of time there has been little incentive for industry to have such data as the Food Standards Code requires a nil tolerance for this organism. If a commercial imperative was present, businesses may invest in obtaining this data to potentially avoid a recall of their products

FSANZ welcomes comment on the need to specify methods of analysis in the Code or whether other mechanisms can be used in order to ensure consistent application of microbiological criteria.

Inclusion of methodology in the Code

NSW does not believe that the current system of specifying methods in the Code is adequate, given that the reference to out-dated AS1766 methods has still been in place for some time. The current approach is not able to reflect the rapid changes occurring in microbiological methods where many newly developed methods may be more rapid and/or sensitive than the traditional cultural methods.

If microbiological testing is conducted in a NATA accredited facility then these facilities would have already undertaken validation. Where rapid tests are undertaken by in-house laboratories for routine testing then these should also be validated according to the AS/NZS 4659 series for equivalence.

The Authority suggests that any microbiology methods that have been accredited for use through Standards Australia or international organisations such as ISO, AFNOR, AOAC, CEN, FSIS MLG, FDA BAM would be suitable for use.

However, it requires consideration on the best way to communicate this to industry, should no standard methodology be specified in the Code. An editorial note in the Code may be appropriate to indicate this or within any assistance material such as a user guide for industry.

FSANZ welcomes comment on the role or need for regulatory limits in Standard 1.6.1 to ensure a safe food supply. Can reference criteria provide adequate support for enforcement agencies (and guidance to industry) to ensure food businesses produce safe and suitable food?

The need for regulatory limits in the Code

The current wording contained in Standard 1.6.1 of the Code is "the criteria for determining when a lot or consignment of food poses a risk to human health and therefore should not be offered for sale". In addition, under the NSW Food Act 2003 unsafe food is defined as "…food is ***unsafe*** at a particular time if it would be likely to cause physical harm to a person who might later consume it…". Therefore the microbiological limits in the Code provide a very important tool for both industry and food safety regulators to determine whether a food is safe or unsuitable, and subsequent actions such as recall or seizure.

At this stage, the Authority cannot support Option 2 to delete the limits in the Code and establish reference criteria. The potential role, applicability and enforceability of reference criteria is not something that has been considered at this point and should form part of the review of the entire Standard 1.6.1. The inclusion of microbiological criteria in the Code provides clear boundaries for compliance/non-compliance, especially in respect to foodborne pathogens. If a review of Standard 1.6.1 determines that reference criteria should play a role moving forward, then the limits for *L. monocytogenes* can be reviewed at that time. The Authority acknowledges that the current limits in Standard 1.6.1 do not necessarily reflect all the high risk food categories, with RTE poultry meat in particular being the cause of several foodborne listeriosis outbreaks in recent years.

Conclusion

The Authority believes that microbiological limits specified in the Code provide certainty for both industry and regulators in what food products must comply with and assist in the determination of safe or unsuitable food. The Authority also considers that Australian limits should align with international best practice and in this regard align with Codex for allowing up to 100 cfu/g of *L. monocytogenes* in products where it can be demonstrated that the organism will not grow in the food during the shelf life. However, clarification is required on whether this would replace the existing limits for specific foods already present in Standard 1.6.1.

The Authority believes that risk assessment information justifies making this change to the Code, as it has been demonstrated that very low doses of *L. monocytogenes* are unlikely to cause adverse public health outcomes and the current limits may result in unnecessary food recalls with little benefit for public health outcomes.

As FSANZ is also aware, amending the limits in the Code would address the current inconsistencies which exist between Standard 1.6.1 of the Code, the *Guidelines for the microbiological examination of ready-to-eat foods* and *Listeria recall guidelines for packaged ready-to-eat foods*.

ENDS

The views expressed in this submission may or may not accord with those of other NSW Government agencies. The NSW Food Authority has a policy which encourages the full range of NSW agency views to be submitted during the standards development stages before final assessment. Other relevant NSW Government agencies are aware of and agree with this policy.

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