Australian Food and Grocery Council

SUBMISSION

JANUARY 2014

TO:
FOOD STANDARDS AUSTRALIA NEW ZEALAND

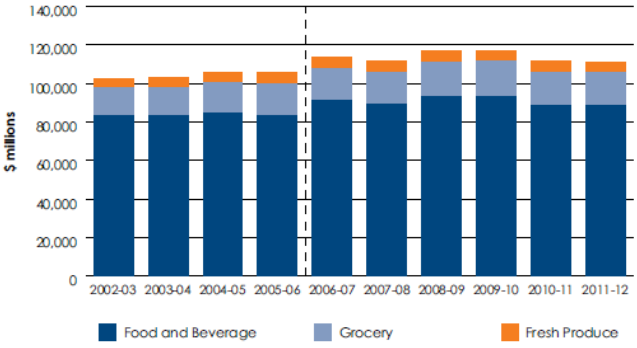
IN RESPONSE TO:
P1017 CRITERIA FOR *Listeria monocytogenes* – MICROBIOLOGICAL LIMITS FOR FOODS

Australian Food and Grocery Council

The Australian Food and Grocery Council (AFGC) is the leading national organisation representing Australia's food, drink and grocery manufacturing industry.

The membership of AFGC comprises more than 180 companies, subsidiaries and associates which constitutes in the order of 80 per cent of the gross dollar value of the processed food, beverage and grocery products sectors.

Figure 4.1: Composition of the industry's turnover ($2011-12)[4]



Source: Based on ABS, catalogue number 8221.0, 8159.0 and 8155.0

With an annual turnover in the 2011-12 financial year of $111 billion, Australia's food and grocery manufacturing industry makes a substantial contribution to the Australian economy and is vital to the nation's future prosperity.

Manufacturing of food, beverages and groceries in the fast moving consumer goods sector[1] is Australia's largest manufacturing industry, accounting for over one quarter of the total manufacturing industry in Australia.

The diverse and sustainable industry is made up of over 25,600 businesses and accounts for over $50 billion of the nation's international trade. These businesses range from some of the largest globally significant multinational companies to small and medium enterprises. This sector spends $535 million a year on research and development.

The food and grocery manufacturing sector employs almost 300,000 Australians, representing almost one third of all manufacturing jobs in Australia, and paying around $12 billion a year in salaries and wages.

Many food manufacturing plants are located outside the metropolitan regions. The industry makes a large contribution to rural and regional Australia economies, with almost half of the total persons employed being in rural and regional Australia[2]. It is essential for the economic and social development of Australia, and particularly rural and regional Australia, that the magnitude, significance and contribution of this industry is recognised and factored into the Government's economic, industrial and trade policies.

1 Fast moving consumer goods includes all products bought almost daily by Australians through retail outlets including food, beverages, toiletries, cosmetics, household cleaning items etc.

2 About Australia: www.dfat.gov.au

1. INTRODUCTION

The Australian Food and Grocery Council (AFGC) welcome the opportunity to make this submission to Food Standards Australia New Zealand (FSANZ) in response to the call for submissions – Proposal P1017 Criteria for *Listeria monocytogenes* – Microbiological Limits for Foods.

The AFGC understands that the key matters to be addressed in this second round of consultation are as follows:

- Move from a product-by-product approach which specifies *L. monocytogenes* limits for specific foods, regardless of individual product characteristics, to an internationally agreed risk-based approach that applies limits broadly to ready-to-eat (RTE) foods based on product and processing characteristics; and

- Review elements of Standard 1.6.1 that are out-dated or unclear such as reference methods of analysis, the purpose of Standard 1.6.1 and the presentation of information within the Schedule to the standard.

The AFGC has developed this response in consultation with its membership of food manufacturers and brand owners, specifically those member companies who are impacted by, or have an interest in, the changes proposed to Standard 1.6.1 as described in P1017.

2. AFGC POSITION

The AFGC continues to **support Option 1** – to include scientifically justifiable, internationally consistent limits in Standard 1.6.1 for *L. monocytogenes* on the basis of whether the food is ready-to-eat and can or cannot support its growth.

The AFGC has some concerns with respect to others matters addressed in this consultation:

- Proposed definition of “ready to eat” to replace the current definition in Standard 3.2.2;
- Purpose – the proposed purpose is inconsistent with the wording of new clause 5;
- Proposed definition of microorganism in clause 1;
- Lack of a stock in trade provision;
- Microbiological limits in foods – there is a change to the scope of this clause from “lot of food” to “a food” which has significant implications;
- Changes to the Schedule in the Standard; and
- The RIS is limited to a very basic cost benefit analysis which focuses only on option 1.

These concerns are outlined in the following section of the submission.

3. SPECIFIC COMMENTS – STANDARD 1.6.1

3.1. Definition of 'ready to eat"

The definition proposed in P1017 is:

*"**ready-to-eat** in relation to food means food that is ordinarily consumed in the same state as that in which it is sold, and –*
(a) does not require further processing (such as cooking), but may be defrosted, reheated or portioned before consumption; and
(b) does not include nuts in the shell and whole, raw fruits and vegetables that are intended for hulling, peeling or washing by the consumer."

The proposed definition of 'ready-to-eat' is not consistent with *Codex Alimentarius* ("Codex") and is also different to the current definition in clause 1 to Standard 3.2.2 (which we note is to be deleted).

The Codex definition makes specific reference to "listericidal steps" making it inappropriate as a general definition, and AFGC agrees that it is preferable to have one consistent definition of "ready to eat" than have the same term carry different meanings in different parts of the Code.

The proposed definition, however, is more prescriptive and inconsistent with other jurisdictions.

The definition used by Health Canada is similar to the existing definition in Standard 3.2.2:

Ready-to-eat (RTE) foods are foods not requiring any further preparation before consumption, except perhaps washing/rinsing, thawing or warming.[3]

The definition used by USFDA in their guidance document is also similar to the existing definition in Standard 3.2.2:

Ready-to-eat (RTE) food means a food that is customarily consumed without cooking by the consumer, or that reasonably appears to be suitable for consumption without cooking by the consumer.[4]

Compared with the current definition in Standard 3.2.2, the proposed definition introduces wording as a new paragraph (a). This new wording makes distinctions that are not explained (e.g. the difference between cooking and re-heating) and is unclear in its intention as to what is proposed as paragraph (b) - why are the steps mentioned in (b) not "further processing" for the purposes of paragraph (a)? It is also confusing because reheating may or may not be listericidal depending on the time and temperature combination applied.

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3 Health Canada, http://www.hc-sc.gc.ca/fn-an/legislation/pol/policy_listeria_monocytogenes_2011-eng.php#appa, accessed 16.12.13

4 GUIDANCE FOR INDUSTRY: CONTROL OF LISTERIA MONOCYTOGENES IN REFRIGERATED OR FROZEN READY-TO-EAT FOODS; DRAFT GUIDANCE FEBRUARY 2008, HTTP://WWW.FDA.GOV/FOOD/GUIDANCEREGULATION/GUIDANCEDOCUMENTSREGULATORYINFORMATION/FOODPROCESSINGHACCP/UCM073110.HTM#OTHERGUI, ACCESSED 02.01.14

These problems arise due to the concept of "the same state" in the wording of the definition. What is intended is that certain non-listericidal transformations (defrosting, portioning, non-listericidal reheating) are to be deemed to be "in the same state" as the food as sold. The wording of the definition needs to better reflect this intention to avoid the uncertainty and confusion described above.

Recommendation:

The AFGC recommends that the definition reverts to the current definition in Standard 3.2.2 OR consideration is given to definitions from other jurisdictions.

3.2. Scope and Purpose

Proposed:

This Standard specifies microbiological food safety criteria, which define the acceptability of a lot or consignment of food[5] *for sale or intended for sale. The Schedule to the Standard sets out sampling plans and the limits that a lot or consignment of food must comply with when sampled. Foods that fail to meet these limits may pose a risk to human health and must not be offered for sale.*

The last line in the proposed wording is inconsistent with the opening line ("food" vs "a lot or consignment of food"). The wording in the current standard is clear that it applies to lots or consignments of a food, not a food generally. This clarity is also lost in the proposed standard which often refers to a "food" rather than to a lot or consignment. To be clear, it is a lot or consignment that passes or fails the Standard. A different lot of the same food needs to be tested independently and may have a different outcome.

Recommendation:

The AFGC recommends that the wording in the Scope and Purpose be amended to reflect that specific lots or consignments of foods may pass or fail tests for compliance with the Standards, rather than indicating that foods generally may, or may not, comply.

3.3. Definitions (clause 1)

Microorganism – although this is only meant to apply in this Standard the definition is somewhat confusing and not required. The AFGC notes that this definition has not been carried through under the Code review (P1025) – it is not present in Division 10 (Microbiological limits for food) 1.157 – Interpretation and does not appear in Schedule 27 – Microbiological limits for foods.

The AFGC notes that other definitions in current clause 1 of Standard 1.6.1 have not been carried through with the Code Review (P1025) except for the definition for Standard Plate Count (SPC). This lack of consistency between proposals has the potential to create confusion.

3.4. Application to stock in trade (clause 2)

The AFGC does not support the nil stock in trade applied under clause 2.This proposal will apply new *Listeria monocytogenes* limits to foods that do not currently require testing, some of which may have a

5 AFGC emphasis

very long shelf life (eg canned ready-to-eat foods). Manufacturers will need to alter their sample, test and retention practices accordingly to ensure compliance. It would be unfair to introduce a new requirement on product that already resides in the supply chain without giving manufacturers the prior opportunity to verify compliance.

Recommendation:

The AFGC recommends that the standard stock in trade provisions apply and the proposed clause 2 is deleted from the amendments to the Standard.

3.5. Microbiological limits in foods (clause 5)

As discussed above under purpose and scope, the AFGC notes that new subclauses 5(1) and 5(2) incorrectly use the term "food":

"A **food**[6] that is listed ….."

"A **food** does not comply with this Standard if…"

Currently clause 5 uses the term "**A lot of food**"

This change from "lot of food" to "food" has significant implications and is inconsistent with the revised purpose statement.

Recommendation:

The AFGC recommends that the term "a lot of food" replaces the term "food" in subclauses 5(1) and 5(2).

3.6. Foods not supporting the growth of *Listeria monocytogenes* (clause 6)

The AFGC support new clause 6

3.7. Schedule to Standard 1.6.1

AFGC notes the following changes to the Schedule to Standard 1.6.1:

- the title "Microbiological Criteria (clause 2)" is replaced with "Microbiological limits in food";
- the heading under Column 2 of the Schedule is changed to "Microorganism/test/toxin" to more correctly reflect what may be included in this column;
- the units currently included in Column 2 are deleted and included under Columns 5 and 6 (note the missed reference to "g" in relation to *B.cereus* in powdered infant formula);
- MPN is included in relation to limits based on this methodology;
- the limits for *Listeria monocytogenes* in nominated foods are deleted and replaced by limits for "Ready-to-eat food in which the growth of *Listeria monocytogenes* will not occur" and "Ready-to-eat food in which the growth of *Listeria monocytogenes* can occur"; and

6 The bolding is AFGC emphasis

- the limits for “powdered infant formula products with added lactic acid producing culture” are deleted as mentioned above.

AFGC supports these changes except for the heading for column 2 - there does not appear to be any toxin assays in Column 2 and the inclusion of “MPN” (discussed below).

The AFGC notes that the proposed format for the Schedule is not consistent with that proposed under the Code review (P1025). The proposed Schedule 27 (Microbiological limits for foods) has combined current columns 1 and 2 reducing the total number of columns to 5. In addition, the headings for the columns have changed – n, c, m and M are no longer present. As previously noted, this inconsistency between proposals is confusing.

Recommendation:

The AFGC recommends consistency between proposed amendments under P1025 and P1017.

3.7.1. Inclusion of MPN

The current Standard specifies microbiological levels (m and M) as a number per reference quantity of the food. The current proposal expands this to indicate that the number is calculated according to the Most Probable Number (MPN) method.

The AFGC cautions that specification of MPN does more than clarify the identity of the numbers specified as m and M for the sampling plan, and emphasises that this will require full and proper impact assessment.

In particular, the current Standard’s omission of “MPN” in columns 5 and 6 of the schedule means that both regulators and companies may use any reputable assay to determine compliance with the microbiological standard. Specifying MPN means that regulators can only take enforcement action based on MPN calculations using an appropriate test method to produce the data for input into the MPN formula, and companies must either do likewise, or else validate their (non-MPN) assay against MPN methods.

It may well always have been the intent that the count numbers be calculated as MPN, and the AFGC certainly accepts the validity of MPN as a means of determining microbial counts. The issue is that specification of MPN in the proposal may have, at least in theory, the same effect as specifying a new test method in terms of the validation that companies must undertake.

Recommendation:

The AFGC does not oppose the specification of MPN in itself, but believes the specification must be subject to an impact analysis of the actual costs of validation where non-MPN methods are currently in use.

3.8. Regulatory Impact Statement (RIS)

FSANZ advise that:

A Regulation Impact Statement has not been prepared as the proposed variations to Standard 1.6.1 are likely to have only a minor impact on business and individuals. (CFS, p26).

FSANZ has not provided justification for this statement. It may be the case, or it may not be – however it is expected FSANZ would provide the reasons for their assessment that the impact on industry is minimal, unless they have already consulted with industry.

The RIS is limited to a very basic cost benefit analysis which focuses only on option 1 for moving from a product by product approach to an agreed risk based approach for RTE foods. The other elements of Standard 1.6.1 which have been reviewed are not addressed in the cost benefit analysis, particularly the proposed exemption from stock-in-trade allowances.

Recommendation:

The AFGC recommend that FSANZ conduct a more detailed RIS in order to assess the impact of all of the proposed changes and not just those resulting from the recommendation of option 1.

4. CONCLUSION

AFGC supports **Option 1** – to include limits in Standard 1.6.1 for *L. monocytogenes* on the basis of whether the food is ready-to-eat and can or cannot support its growth.

AFGC does not support other changes proposed for Standard 1.6.1 and recommend that:

- FSANZ conduct a more detailed RIS in order to assess the impact of all of the proposed changes and not just those resulting from the recommendation of option 1; OR
- Defer these changes for consideration under a more comprehensive review of Standard 1.6.1; OR
- Defer these changes for consideration under P1025.

The AFGC stand ready to provide further industry perspectives on P1017 should they be required.

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Australian Food and Grocery Council

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