

16 March 2012

[6-12]

APPLICATION A1045 BACTERIOPHAGE PREPARATION P100 AS A PROCESSING AID 2nd Call for submissions

Executive Summary

Purpose

FSANZ received an Application from EBI Food Safety Ltd¹ to amend the *Australia New Zealand Food Standards Code* (the Code) to permit the use of a bacteriophage (*Listeria* phage) preparation Listex P100 (designated P100 in this Report) as a processing aid. The Applicant stated that the purpose of their Application was to “eradicate or decrease *Listeria monocytogenes* on various ready-to-eat (RTE)² food products for human consumption”. FSANZ confirmed with the Applicant that the request was for solid RTE products and did not include any liquid products.

Background

Bacteriophage infect and kill bacterial cells through a mechanism termed lysis, where the bacterial cell wall is broken down by bacteriophage enzymes, therefore preventing replication and spread of the host bacteria.

Bacteriophages are the most abundant biological entities on earth – being present wherever bacteria exist. They infect specific strains of bacteria so the P100 bacteriophage would not infect any other bacteria except *Listeria*. They are unable to infect plant, animal or human cells.

RTE foods are prepared and sold in a form that enables the food to be consumed usually without further preparation. Certain solid RTE products at risk of *L. monocytogenes* contamination may be treated with P100 if approval is granted.

The Application is assessed under the Major procedure which includes two rounds of public consultation. The major issues raised in submissions to the 1st Assessment Report were:

- resistance development and maintenance of efficacy over time
- technological function as a processing aid or a food additive

¹ Now called Microcos B.V.)

² There is an existing definition for RTE food in Chapter 3.2.2 of the Code: **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.

- labelling requirements for use as a processing aid
- types of foods for which permissions should be given
- specification and analytical methods
- enforcement and implementation

This report contains additional information to that provided in the 1st Assessment Report together with responses to comments raised by submitters. This Report also provides an opportunity to make submissions on the proposed draft amendments to the Code.

Risk Assessment

FSANZ has assessed the scientific evidence submitted by the Applicant and other peer-reviewed scientific information.

The stated purpose for P100 is to reduce or eliminate *L. monocytogenes* in a range of RTE foods. The evidence presented to support this use provides adequate assurance that the bacteriophage preparation, in the form and amounts proposed by the Applicant, is technologically justified and has been demonstrated to be effective in achieving its stated purpose. The studies assessed to make this conclusion investigated the effects on solid RTE meat (including poultry) and meat products, cheese, fish and fish products, and fruits and vegetables and their products.

FSANZ's concluded that P100 was efficacious when applied in high concentrations (generally, $>10^8$ pfu/cm²)³, that are several orders of magnitude greater than the *L. monocytogenes* contaminant load on the food surface. The strategy applied is called a "single hit" application which eliminates small numbers of bacterial cells by treating with a significantly greater concentration of bacteriophages.

P100 has no ongoing function on the final treated solid food as phage particles bind to the food surface relatively soon after treatment (within 24 hours), and are therefore unable to locate and destroy bacteria which may subsequently re-contaminate the food.

FSANZ reviewed evidence examining potential toxicity associated with the P100 preparation. There were no hazards identified which would preclude permitting the use of the P100 preparation to treat food for the stated purpose. In assessing the allergenicity and toxicity of the P100 preparation, a comparison of the genomic sequences of P100 proteins and known allergens and toxins was carried out. No biologically significant similarity was found between the genes coding for the P100 proteins and any known allergens or toxins. FSANZ has concluded that P100 poses no risk to public health and safety for Australian or New Zealand consumers.

FSANZ reviewed the information on the possibility of emergence of P100 resistant mutants of *L. monocytogenes*. FSANZ concluded that resistance development to phage treatment is minimal in food processing environments when appropriate user instructions are provided and adhered to. FSANZ further concluded that there would be no negative impact on humans caused by the ingestion or contact with P100.

The key risk assessment findings are detailed in **Supporting Document 1 (SD1)**.

Risk Management

P100 is classified as a processing aid for the stated purpose of this Application because the conclusion of the risk assessment is that it has no ongoing technological function in solid RTE foods.

³ Plaque forming units

Permission is proposed for applying P100 to surface treat specific solid RTE foods at risk of *L. monocytogenes* contamination (being RTE meat and meat products, cheese, fish and fish products, and fruit and vegetables and their products). FSANZ also proposes an added clarification to the permission sought in the Application that solid RTE food covered in a liquid is not covered by this permission.

The permission is proposed to be within the Table to clause 14 – Permitted processing aids with miscellaneous function, under conditions of Good Manufacturing Practice (GMP).

FSANZ does not propose to include further requirements in the permission or specification to ensure maintenance of efficacy of the P100 preparation. This is because the commercial practicalities of ensuring that P100 is efficacious, and that it is used under principles of GMP are relevant to both the supplier of P100 and the food manufacturer using the preparation.

Currently there are no specifications for P100 in the Code. Therefore a new specification has been drafted for incorporation into the Schedule of Standard 1.3.4 – Identity and Purity.

Processing aids permitted under Standard 1.3.3 are exempt from labelling under subclause 3(d) of Standard 1.2.4 – Labelling of Ingredients. FSANZ has considered the various arguments for requiring labelling of P100 for treated food and it confirms the earlier view that, consistent with the current exemption, labelling is not warranted and if mandated, may potentially create consumer concerns.

Assessing the Application

In assessing the Application, FSANZ had regard to the following matters as prescribed in section 29 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act):

- whether costs that would arise from a food regulatory measure developed or varied as a result of the Application outweigh the direct and indirect benefits to the community, Government or industry when permitting P100 as a processing aid in certain solid RTE foods
- whether other measures would be more cost-effective than a variation to Standard 1.3.3 that could achieve the same outcomes
- any relevant New Zealand standards
- other relevant matters.

Preferred Approach

To prepare a draft variation to the Table to clause 14 of Standard 1.3.3 – Processing Aids to add *Listeria* phage P100 as an approved processing aid for the surface treatment of solid ready-to eat meat and meat products (including poultry), fish and fish products, fruit and fruit products, vegetables and vegetable products and cheese.

To prepare a draft variation to Standard 1.3.4 – Identity and Purity to include a specification for P100 in the Schedule.

Reasons for Preferred Approach

The preparation of a draft amendment to the Code to allow the use of P100 as a processing aid in Australia and New Zealand is proposed for the following reasons:

- The safety assessment did not identify public health and safety concerns.
- The assessment concluded that, for the purpose proposed by the Applicant, P100 has a technological function as a processing aid in solid RTE foods. It has no ongoing technological function in these foods.
- The assessment concluded that P100 is likely to have an ongoing technological function in liquids. Therefore liquid, semi-solid and solid RTE foods covered in a liquid are excluded from this permission.
- The COAG Legislative and Governance Forum on Food Regulation (the Forum) ⁴ policy guidance on the *Addition to Food of Substances other than Vitamins and Minerals*.
- There are no other measures that would be more cost-effective than a variation to Standard 1.3.3 that could achieve the same outcome.

Consultation

Public submissions were invited on the 1st Assessment Report between 20 September and 1 November 2011. Comments were specifically sought on the scientific aspects, in particular the safety and technological function assessments, the P100 specification and parties that may be affected by the Application.

Nine submissions were received. The summary of the issues from the received submissions and FSANZ's response to these are provided in Table 2 in Section 10.1 of this report.

Submissions are now sought on the proposed draft variations to the Code and FSANZ's responses to issues raised in submissions to the 1st Assessment Report.

Invitation for Submissions

FSANZ invites public comment on this Report based on regulation impact principles for the purpose of preparing an amendment to the Code for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist FSANZ in further considering this Application. Submissions should, where possible, address the objectives of FSANZ as set out in section 18 of the FSANZ Act. Information providing details of potential costs and benefits of the proposed change to the Code from stakeholders is highly desirable. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

The processes of FSANZ are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of FSANZ and made available for inspection. If you wish any information contained in a submission to remain confidential to FSANZ, you should clearly identify the sensitive information, separate it from your submission and provide justification for treating it as confidential commercial material. Section 114 of the FSANZ Act requires FSANZ to treat in-confidence, trade secrets relating to food and any other information relating to food, the commercial value of which would be, or could reasonably be expected to be, destroyed or diminished by disclosure.

Submissions must be made in writing and should clearly be marked with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website using the Changing the Code tab and then through Documents for Public Comment.

⁴ Formerly called the Australia and New Zealand Food Regulation Ministerial Council

Alternatively, you may email your submission directly to the Standards Management Officer at submissions@foodstandards.gov.au. There is no need to send a hard copy of your submission if you have submitted it by email or the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 27 April 2012

SUBMISSIONS RECEIVED AFTER THIS DEADLINE WILL NOT BE CONSIDERED

Submissions received after this date will only be considered if agreement for an extension has been given prior to this closing date. Agreement to an extension of time will only be given if extraordinary circumstances warrant an extension to the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions relating to making submissions or the Application process can be directed to the Standards Management Officer at standards.management@foodstandards.gov.au.

If you are unable to submit your submission electronically, hard copy submissions may be sent to one of the following addresses:

**Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
AUSTRALIA
Tel (02) 6271 2222**

**Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6143
NEW ZEALAND
Tel (04) 978 5630**

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SUPPORTING DOCUMENTS

The following material, which was used in the preparation of this Assessment Report, is available on the FSANZ website at

<http://www.foodstandards.gov.au/foodstandards/applications/applicationa1045bact4797.cfm>

SD1 Risk Assessment Report (updated)

INTRODUCTION

FSANZ received an Application from EBI Food Safety Ltd⁵ to amend the *Australia New Zealand Food Standards Code* (the Code) to permit the use of a bacteriophage (*Listeria* phage) preparation Listex P100 (subsequently called P100 in this report). The permission was sought as a processing aid “to eradicate or decrease *Listeria monocytogenes* on various ready-to-eat (RTE)⁶ food products for human consumption”. FSANZ confirmed with the Applicant that the request was specifically for solid RTE foods at risk of *L. monocytogenes* contamination and did not include liquid products. The Applicant claims P100 acts as a processing aid in RTE foods and so requested that Standard 1.3.3 – Processing Aids be amended.

Background information on bacteriophages and the potential for contamination of RTE foods with *L. monocytogenes* was provided in the 1st Assessment Report for A1045. This 2nd Assessment Report contains additional information to that provided in the 1st Assessment Report, responses to comments raised by submitters and the proposed draft amendments to the Code.

1. The Issue / Problem

The Applicant has requested that P100 be approved as a processing aid to reduce levels of *L. monocytogenes* on the surfaces of RTE food.

There is currently no permission in the Code for the use of bacteriophage preparations as processing aids. A safety assessment of the use of P100 as a processing aid is required and must be undertaken before any permission may be granted. This assessment includes the consideration of the safety of the P100 preparation; whether it performs its stated technological function, and the types of food that may be treated.

2. Current Standard

2.1 Background

The use of processing aids is regulated by Standard 1.3.3. The purpose of this Standard includes a definition for ‘processing aids’ which is as follows:

Processing aid means a substance listed in clauses 3 to 19, where –

- (a) the substance is used in the processing of raw materials, foods or ingredients, to fulfil a technological purpose relating to treatment or processing, but does not perform a technological function in the final food; and*
- (b) the substance is used in the course of manufacture of a food at the lowest level necessary to achieve a function in the processing of that food, irrespective of any maximum permitted level specified.*

Clause 14 (permitted processing aids with miscellaneous functions) is the most applicable clause.

⁵ Now called Microcos B.V.

⁶ There is an existing definition for RTE food in Chapter 3.2.2 of the Code: **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.

The use of food additives is regulated by Standard 1.3.1 – Food Additives. The purpose of this Standard includes a definition for food additives:

A food additive is any substance not normally consumed as a food in itself and not normally used as an ingredient of food, but which is intentionally added to a food to achieve one or more of the technological functions specified in Schedule 5.

2.2 Overseas approvals

The European Food Safety Authority (EFSA) issued a scientific opinion on the use of bacteriophages in food products and concluded that each phage/food application should be considered on a case-by-case basis taking into consideration the biology and safety aspects of each bacteriophage and the food matrix to which it is applied (EFSA 2009).

On 14 July 2009, the Dutch Ministry of Public Health permitted the use of P100 as a processing aid for use on all foods in The Netherlands.

P100 was granted Generally Recognised as Safe (GRAS) status by the United States Food and Drug Administration (FDA) in 2006 for use as a processing aid in cheese and in 2007, extended its use to all food products susceptible to *L. monocytogenes*. Ingredient labelling requirements were initially specified for P100-treated meat and poultry products by the Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA). However, in 2011, USDA permitted its use as a processing aid on the surface of RTE meat and poultry products to achieve a level of 10^7 to 10^9 plaque forming units (pfu) per gram, without the need for labelling. The letter of permission requires that the treatment is integrated into the HACCP programs of the industry.

On 3 September 2010, Health Canada issued a 'letter of no objection' for the use of P100 as a processing aid in several foods; 'mainly deli meat and poultry products (e.g. wieners, sliced ham), cold-smoked fish, vegetable prepared dishes, soft cheeses and/or other dairy foods'. A recommendation was made to provide clear instructions on the conditions of application to potential users. A proposed level of use within the range of 10^7 to 10^9 pfu/g was also specified.

3. Objectives

The objective of this assessment was to determine whether it is appropriate to amend the Code to permit the use of P100 as a processing aid. In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in section 18 of the FSANZ Act. These are:

- the protection of public health and safety; and
- the provision of adequate information relating to food to enable consumers to make informed choices; and
- the prevention of misleading or deceptive conduct.

In developing and varying standards, FSANZ must also have regard to:

- the need for standards to be based on risk analysis using the best available scientific evidence;
- the promotion of consistency between domestic and international food standards;

- the desirability of an efficient and internationally competitive food industry;
- the promotion of fair trading in food; and
- any written policy guidelines formulated by the Ministerial Council.

The COAG Legislative and Governance Forum on Food Regulation (the Forum) Policy Guideline, *Addition to Food of Substances other than Vitamins and Minerals*, includes specific order policy principles for substances added to achieve a solely technological function, such as processing aids. These specific order policy principles state that permission should be permitted where:

- the purpose for adding the substance can be articulated clearly by the manufacturer as achieving a solely technological function (i.e. the 'stated purpose'); and
- the addition of the substance to food is safe for human consumption; and
- the amounts added are consistent with achieving the technological function; and
- the substance is added in a quantity and a form which is consistent with delivering the stated purpose; and
- no nutrition, health or related claims are to be made in regard to the substance.

The main objective which applies to this assessment is the primary objective of protection of public health and safety.

4. Questions to be answered

For the purpose of the Application, FSANZ considered the following risk assessment questions:

- Is P100 suitably well characterised?
- Does P100 achieve its stated technological purpose?
 - Has the technological need been articulated clearly?
 - Is the preparation added in a quantity and form which is consistent with delivering the stated purpose?
 - Can development of resistance render P100 ineffectual?
- Does P100 present any food safety issues?
 - Are there potential allergens present in P100?
 - Are there toxicological safety issues?

RISK ASSESSMENT

In addition to information supplied by the Applicant, other available resource material including published scientific literature and general technical information was used in this assessment.

The summary and conclusions from the risk assessment, provided in **Supporting Document 1** (SD1), are presented below. SD1 has been slightly amended from the document provided with the 1st Assessment Report.

5. Risk Assessment Summary

5.1 Characterisation

5.1.1 *Is P100 suitably well characterised?*

The Applicant had provided information detailing the identity of P100 as belonging to the Order *Caudovirales*, family *Myoviridae*. Since the 1st Assessment Report, additional information has been provided that further characterises P100 as belonging to the subfamily *Spounaviridae*, genus Twort-like, and species designated *Listeria* phage P100. The host (production) organism is a non-pathogenic type strain of *Listeria innocua* (ATCC 33090, DSM 20649, NCTC 11288, SLCC 3379). P100 and the production organism are completely characterised. Section 4 in SD1 provides the detailed analysis for this conclusion.

5.2 Technological function

5.2.1 *Does P100 achieve its stated technological purpose?*

FSANZ has made an assessment of the efficacy and the possibility of an ongoing technological function when P100 is used for the stated purpose. P100 was effective in reducing numbers of *L. monocytogenes* on treated foods (see section 5.2 and annex 1 of SD1 for more detail of FSANZ's analysis of efficacy studies of P100 and comparable phage preparations). The specific food matrices assessed were sliced ham, turkey breast, hot dogs, Brazilian fresh sausage, salmon fillet, catfish fillet, mixed seafood, smoked salmon, various cheeses, lettuce and cabbage. A number of liquid foods (chocolate milk) and solid food covered in liquid (Mozzarella cheese in brine) were also assessed. If the applied P100 preparation did not fully eliminate the *L. monocytogenes* contamination then the growth rate of *L. monocytogenes* would be the same as for untreated product, but from a lower initial concentration.

It can be concluded that for P100 to be effective in treating food:

- the initial treatment concentration should be large (in the order of 10^8 pfu/cm²) and optimised for each product and production process
- the phage preparation should be applied to the surface of the food at the recommended concentration and duration

When applied to solid foods, phage particles bind to the surface of the food soon after treatment, resulting in immobilisation and reduced ability to locate bacteria remaining on the surface (or subsequent re-contamination). The phage particles may not be destroyed, but they are no longer functional. The overall weight of evidence supported the conclusion that P100 had no ongoing technological function in solid RTE food when used as proposed by the Applicant.

This is not the case for treatment of liquid foods where the phages are quite mobile and so have a high probability of locating bacteria in the liquid. In liquid foods (e.g. chocolate milk) and those covered with a liquid (e.g. Mozzarella cheese in brine) phages may have an ongoing technological function, as the results assessed in Section 5.2.2.2 and annex 1 of SD1 indicate.

No data had been supplied to enable an assessment of the technological function of P100 in semi-solid foods (such as yoghurt).

5.2.2 *Does P100 lose its efficacy due to resistance development by host bacteria?*

The risk assessment reviewed the information on the possibility of emergence of bacteriophage-resistant strains of *L. monocytogenes* (see section 5.3 of SD1). The conclusion from the scientific evidence, supported by experts in the field and international regulators, is that when using bacteriophages to treat food, the development of resistance in food processing environments is minimal, provided adequate information on the use, application and disposal of unsold product is provided to food manufacturers, and that manufacturers have regard to that information. This is no different to resistance developed by bacteria as a stress response to other bactericidal treatments applied during food processing. Treated products are not expected to re-enter the processing facility. Adherence to GHP ensures phage treated product that is not appropriate to be processed for commercial sale will be removed from the production facility on a regular basis, along with appropriate cleaning regimes to ensure there is no build-up of bacteriophage reservoirs in the facility. Continuous screening and monitoring of host susceptibility and phage resistance development in food premises using the P100 preparation, are being maintained by the Applicant.

5.3 Safety Assessment

5.3.1 *Does the P100 preparation present any food safety issues?*

No food safety issues were identified from the available toxicity data. This conclusion was supported by the absence of biologically significant homology between the P100 proteins and any known allergens or toxins.

P100 bacteriophage was only effective against bacteria of the genus *Listeria*. It cannot infect plant, animal or human cells. Ingestion or contact with P100 did not present a public health risk (see Section 6 in SD1).

FSANZ is not aware of any current or proposed medical uses of P100. Therefore, detrimental medical effects from treating specific food types with P100 as a processing aid are not expected.

5.4 Conclusion

The findings of the risk assessment for this Application concluded that the use of the P100 preparation was completely characterised, technologically justified and safe for use on solid RTE foods as proposed by the Applicant. There were no ongoing technological functions performed by the P100 preparation in solid RTE foods. This is not the situation for liquid foods or solid foods covered in liquids. Semi-solid foods were not evaluated as no studies were available for assessment.

It was concluded that P100 is likely to maintain its efficacy (not develop reduced sensitivity to *L. monocytogenes*) provided appropriate GHP are maintained by the food manufacturers and an ongoing assessment of efficacy is performed by the Applicant.

RISK MANAGEMENT

6 Risk Management Issues

The conclusions of the risk assessment were that the use of P100 was technologically justified and it was safe for use on solid RTE foods. FSANZ has considered the risk management matters relevant to the Application.

6.1 Technological function: processing aid or food additive?

An important regulatory issue relates to the technological function performed by the Applicant's phage preparation. The purpose statement in the Application is "to eradicate or decrease *L. monocytogenes* on various RTE food products for human consumption". FSANZ assessed how P100 (and comparable phage preparations) performed their technological function i.e. whether it was effective during processing only (therefore to be considered as a processing aid) or in the final food (therefore to be considered as a food additive) (see Section 2.1). Section 5.2.3 of SD1 concluded that P100 performed its technological function during the processing and manufacture of food and had no ongoing technological function in solid foods. It was further concluded that phages that may remain on the surfaces of treated food do not have any active technological function to further reduce *L. monocytogenes* after the initial reduction or possible recontamination.

There is an important distinction between being able to isolate so called 'active' phages from treated food surfaces, even after several days' storage and these phages having functionality to seek, locate and destroy bacteria. It was concluded by analysing the results of the studies, that the phages may be 'bound' to the food surfaces and had limited mobility on solid foods to locate and destroy remaining *L. monocytogenes* and therefore had no ongoing functionality.

The situation was different for liquid foods (for which no permission was sought). Phages had greater diffusion in liquid media and so had a greater likelihood of locating and destroy bacteria on an ongoing basis than when bound or less mobile on solid media.

FSANZ concluded that P100 acted as a processing aid, and not as a food additive, in solid RTE food products for the purpose of reducing levels of *L. monocytogenes* in these foods.

6.2 Proposed regulatory permissions

Based on the conclusions in Sections 5.4 and 6.1 of this Report, FSANZ concludes that it is appropriate to permit P100 as a processing aid to treat specific solid RTE foods and it therefore proposes to amend Standard 1.3.3. The proposed permission is to permit the use of P100 under conditions of Good Manufacturing Practice (GMP) in appropriate processed foods in the Table to clause 14 – Permitted processing aids with miscellaneous function, for which its use has been assessed to be both safe and efficacious. P100 is proposed to be permitted as a processing aid for certain solid RTE foods, specifically meat (includes poultry) and meat products, cheese, fish and fish products, and fruits and vegetables and their products.

It is proposed that the existing definition for RTE food in Chapter 3.2.2 of the Code be applied in relation to this permission.

FSANZ is proposing that solid RTE foods covered in a liquid are excluded from the permission. This is because the intended purpose of the Application is for P100 to function as a processing aid, where it does not perform an ongoing technological function in the final food.

Generally, phages applied to a liquid move freely, and therefore capable of performing an ongoing technological function. Permission is not proposed for semi-solid foods since studies on these products were not provided by the Applicant.

6.3 Risk management approaches to ensure efficacy

Food manufacturers will need to determine appropriate process optimisation and SOP's to establish efficacy on a case-by-case basis for different foods and different production plants. Also, appropriate monitoring of efficacy will be required by food manufacturers and the P100 suppliers.

Following issues raised by submitters, FSANZ sought further information from the Applicant on how they ensure that their P100 preparation does not lose its efficacy in reducing the concentration of *L. monocytogenes* on treated food.

The Applicant performs regular testing of their P100 commercial preparation in association with users to ensure the product has not 'drifted' from the specification. This includes host range testing to ensure that the phage remains active against known, susceptible strains of *L. monocytogenes*, and stability testing of the P100 parent stock using polymerase chain reaction (PCR) methods. Full genomic analysis is conducted on a five-year basis. This was last performed in 2010, and P100 has been confirmed to be consistent with the original sequence deposited in the public domain by the Swiss Federal Institute of Technology. Genetic mutation by the removal or insertion of genes leading to differences in the genomic sequence of the phage could potentially mean the preparation would no longer be considered P100 and would therefore be non-compliant to the specification. A new Application would be required before such a bacteriophage would be permitted for use.

For monitoring purposes, sensitivity tests are conducted on *L. monocytogenes* strains isolated from users' food premises using standardised methods such as efficiency of plating (EOP) tests and pull-down assays. To date, there had been no evidence of reduced susceptibility of *L. monocytogenes* to P100 found by their long term customers⁷. Adherence to GHP is essential as any phage-treated product that is not offered for sale needs to be removed from the production facility on a regular basis and disposed of with care. It also requires that appropriate cleaning regimes are in place to prevent any build-up of bacteriophage reservoirs within the facility. P100 is applied on the food surface in a controlled manner and is not meant to be used as a disinfectant or general bactericide to treat surfaces and equipment within the food processing environment for the elimination or reduction of *L. monocytogenes*. Its use is purely to reduce the concentrations of *L. monocytogenes* that contaminate the surfaces of food products that are processed and packed in the facility. Other GHP methods to reduce bacterial contamination of the equipment are required.

The use of GHP by food manufacturers for the use of P100 in the production of food will be no different to standard practices used for all food production to ensure consistent production of safe food.

Food manufacturers should recognise that treating their food with P100 will not change the nature (whether or not the food supports the growth of *Listeria*) or susceptibility of their food to be re-contaminated with *L. monocytogenes*. The risk category of the food does not change.

⁷ The Applicant has patented P100. Therefore consideration has only been given in this assessment to the control practices of the Applicant.

6.4 Labelling implications

General provisions for the labelling of ingredients, including processing aids, are contained in Standard 1.2.4 – Labelling of Ingredients. Paragraph 3(d) of this Standard exempts processing aids from the requirement to be listed in a statement of ingredients.

In the 1st Assessment Report, FSANZ concluded that P100 functions and is classified as a processing aid for the Applicant's proposed purpose. Therefore, P100 would not be required to be listed in an ingredient list.

In response to the 1st Assessment Report, one submitter stated that the use of a live organism as a processing aid is unprecedented and supported an individual and unique approach to labelling. Another submitter considered that the classification of P100 as a processing aid and subsequent exemption from labelling would deceive consumers.

FSANZ has considered whether ingredient labelling of solid RTE foods that have been treated with P100 is warranted. Labelling is intended to address the objective set out in paragraph 18(1)(b) of the FSANZ Act; the provision of adequate information relating to food to enable consumers to make informed choices. In particular, ingredient labelling provides consumers with information on what ingredients (including food additives) have been added to the food. Because processing aids do not perform a technological function in the final food, they are not labelled as it does not provide useful information for consumers. Rather, such labelling could be misleading or confusing to consumers. Consumers have not expressed concerns on the use of P100 on foods during the first round of submissions.

FSANZ acknowledges the application of a bacteriophage preparation is a new treatment method for reducing the pathogen load in food. However, FSANZ does not support an individual approach to labelling for the following reasons.

- Although P100 is a new treatment method, FSANZ is of the view that 'newness' is not in itself a reason to require labelling. The assessment has concluded that P100 is safe for use as a processing aid for treating solid RTE foods. Under current requirements in the Code, processing aids are, in most cases, exempt from the requirement to be declared in the statement of ingredients.
- The Code does not generally mandate labelling for methods of production or processes used in the manufacture of food. The exceptions to this are:
 - labelling of genetically modified food
 - labelling of irradiated food, and
 - a process declaration where the fatty acid composition of edible oils has been altered.

In relation to genetic modification, processing aids must be labelled when novel DNA and/or novel protein from the processing aid remains present in the final food. In such cases, the name of the processing aid must be declared in the list of ingredients in conjunction with the statement 'genetically modified'.

The remaining processes (irradiation and process declaration where the fatty acid composition of edible oils has been altered) do not relate to the use of processing aids.

- The safety assessment has concluded P100 is safe for the proposed use and any presence post-treatment is likely to be in minute amounts.

FSANZ therefore considers that it would be difficult to declare the P100 preparation in a manner that provides meaningful information to consumers.

- The regulatory approach proposed by FSANZ is consistent with the regulatory approach adopted by the USA, Canada and the Netherlands. These countries do not require P100 to be labelled.

For these reasons, FSANZ does not consider it necessary to depart from the current exemption from labelling for processing aids for P100 for the proposed purpose for treating solid RTE foods.

Another submitter referred to Recommendation 28 of the recent report of the independent Review of Food Labelling Law and Policy, *Labelling Logic*. Recommendation 28 said:

That as a general principle all foods or ingredients that have been processed by new technologies (i.e. all technologies that trigger pre-market food safety assessments) be required to be labelled for 30 years from the time of their introduction into the human food chain; the application of this principle to be based on scientific evidence of direct impact on, or modification of, the food/ingredient to be consumed. At the expiry of that period the mandatory labelling should be reviewed.

The submitter noted that the use of a 'live organism' as a processing aid is unprecedented and there may be consumer expectation that treated foods are labelled to indicate the use of bacteriophages in their processing. However, FSANZ notes that in the response to the Review (released since this submission was received), the Forum agreed not to pursue recommendation 28 *but instead considers that it is appropriate for FSANZ to continue to apply a case-by-case approach to labelling requirements for new technologies*. FSANZ notes that the Forum also agreed to develop a Ministerial Policy Guideline for the case-by-case consideration of regulatory (i.e. labelling) and non-regulatory measures applying to food produced using a new technology requiring a pre-market safety assessment⁸.

Representations made on the label about treated solid RTE foods must also not be misleading or deceptive. Representations about food are subject to the requirements of the Australian *Competition and Consumer Act 2010*, the New Zealand *Fair Trading Act 1986*, and the Australian state and territory Food Acts and fair trading laws. Manufacturers may be liable for penalties where representations about a food are found to be misleading or deceptive.

6.5 Analytical methods for determining presence of P100 in food

The Applicant has provided analytical methods for determining the presence of P100 in food which are summarised below from Section 4.5 in SD1.

A standard agar overlay method can be employed; whereby a dilution or suspension of the bacteriophage treated food sample is mixed in a small volume of molten agar containing host bacteria (e.g. *L. innocua*) and poured onto the surface of a nutrient agar plate. Following overnight incubation, the host bacterial cells grow uniformly throughout the top agar layer (forming a bacterial 'lawn'). The bacteriophage infects the bacteria causing lysis of the bacterial cells, thereby forming clear areas on the bacterial lawn (plaques). Plaques are enumerated resulting in the bacteriophage titre.

⁸ The Review report 'Labelling Logic' and the whole-of-government response to this report (refer to pages 33-35) can be accessed from the Food Labelling Review website at: <http://www.foodlabellingreview.gov.au/internet/foodlabelling/publishing.nsf/content/home>

The Application contains information relating to a PCR method applicable for determining the presence of P100 bacteriophage on treated food. To confirm the presence of P100, the following primers are used: Forward: 5'-ccttcacgcacatcttggttacag (binds P100 genome bp: 108867-108888); reverse: 5'-cagggttgatttaggtactc (binds P100 genome bp: 109957-109937). The time/temperature details for performing the PCR reaction are supplied. This analytical method is available and could be used by analytical laboratories for enforcement purposes if required.

6.6 Specification for P100 *Listeria* phage preparation

There are currently no specifications for bacteriophages, or specifically P100, in any of the primary or secondary references for specifications or in the Schedule for Standard 1.3.4 – Identity and Purity. Therefore, a P100 specification is required in the Schedule for Standard 1.3.4. The proposed specification for P100 is provided below. Specifications for lead and arsenic are addressed by the additional requirements of clause 4 of Standard 1.3.4. The Applicant has demonstrated that the P100 preparation is manufactured according to GMP.

This specification would permit P100 *Listeria* phage preparations though similar, but non-identical phage preparations such as A511, would not be permitted.

Biological classification for the P100 preparation is listed in Table 1. The specification has been expanded and made more definitive compared to that proposed in the 1st Assessment Report since FSANZ has located a more recent and definitive classification of P100.

The Application provided product specifications including microbial limits for the P100 preparation. The Applicant also provided results confirming production of the preparation to meet these microbial limits. FSANZ assessed the specifications and results and concluded that there is no need to include microbial limits as part of the P100 specification. There are no concerns that the Applicant cannot produce the P100 preparation without microbial contamination.

Table 1: Proposed specifications for P100 *Listeria* phage preparation

<i>Biological classification</i>	
Order	<i>Caudoviridae</i>
Family	<i>Myoviridae</i>
Subfamily	<i>Spounaviridae</i>
Genus	Twort-like
Species	<i>Listeria</i> phage P100
<i>Genomic classification</i>	
GenBank Accession Number	DQ004855

7. Options

Two options were considered by FSANZ for the 1st Assessment Report of this Application. The options considered were:

Option 1 Prepare a draft food regulatory measure

Option 1 was the preferred option. The impact analysis following the 1st Assessment has not changed at this stage.

Option 2 Reject the Application

8. Impact Analysis (RIS ID: 12065)

FSANZ is required to consider the impact of various regulatory and non-regulatory options on all sectors of the community, especially relevant stakeholders who may be affected by this Application. The costs and benefits associated with the proposed amendments to the Code have been analysed using regulatory impact principles. The level of analysis is commensurate to the nature of the Application and significance of the impacts. In accordance with the Best Practice Regulation Guidelines, completion of a preliminary assessment for this Application indicated a low or negligible impact. The Office of Best Practice Regulation (OBPR) provided a standing exemption from the need to assess if a Regulation Impact Statement is required for applications relating to processing aids as they are minor or machinery in nature and their use would be voluntary.

8.1 Affected Parties

The affected parties for this Application may include:

- Sectors of the food manufacturing industry who may wish to use P100 to reduce the incidence of *L. monocytogenes* on the foods they process. These manufacturers will be able to take advantage of a new technology which will permit them to market products with increased confidence and to broaden their product range.

An initial cost may be incurred in developing and implementing this new measure. Manufacturers may need to manage consumer response to this new technology.

- Food enforcement agencies responsible for ensuring compliance with the Code may require the development of skills relating to the verification and inspection applicable to a new technology.
- Laboratories may require training on aspects of testing associated with bacteriophage technology.
- Consumers who rely on food manufacturers to produce safe food for them to purchase.

8.2 Cost Benefit Analysis

8.2.1 Option 1 – Prepare a variation to Standard 1.3.3.

L. monocytogenes is a major food safety concern for RTE food as confirmed by FSANZ's most recent recall information. Recalls due to *L. monocytogenes* alone have amounted to 48% of the total number of recalls due to microbiological contamination. This is despite the application of currently available technologies by food manufacturers.

FSANZ's risk assessment concludes that P100 is technologically justified and safe for use in solid RTE foods as proposed by the Applicant to reduce the levels of *L. monocytogenes*. Therefore, its use as an additional new technology by food manufacturers has been considered safe and appropriate for use. The proposed use is a benefit to both producers and consumers of processed food through providing an alternative approach to ensuring the production of safe solid RTE food.

The use of P100 for the proposed purpose is voluntary. Food manufacturers will use a range of factors to determine which techniques best suit their purpose. Such factors will include cost, suitability for the desired purpose, any consumer issues and the net benefit of using the processing aid in food preparation.

Approving a new processing aid may impose a modest added cost to government enforcement agencies, to widen the scope of their activities. Jurisdictions may require familiarisation with this technology and integrate its potential use into their existing food regulatory framework.

8.2.1 Option 2 – Reject the Application

This option would disadvantage those members of the food industry who wish to use P100 as an additional process step to reduce the concentrations of *L. monocytogenes* on RTE food.

There are no benefits to relevant stakeholders of this option.

8.3 Comparison of Options

FSANZ concluded that Option 1 has the greater net benefit. P100 raises no public health and safety issues, offers benefits to food manufacturers and ultimately consumers by having an alternative approach to reduce the levels of a food borne pathogen *L. monocytogenes* on solid RTE food, and is unlikely to pose a significant financial burden (noting possible government costs) on any sector of the community.

Communication and Consultation Strategy

9 Communication

An enhanced communication strategy was developed for this Application because this is the first time FSANZ has assessed a bacteriophage preparation to be used as a processing aid to control a foodborne pathogen (*L. monocytogenes*).

Communication included a website fact sheet; a media release at the start of consultation; and a news item in Food Standards News. A further media release will be developed announcing the call for submissions on the second assessment report.

FSANZ considers standard matters in an open, accountable, consultative and transparent manner. Public submissions are invited to obtain the views of interested parties on issues raised by the Application and the effects of regulatory options. Issues raised in public submissions are evaluated and addressed in assessment reports prepared by FSANZ.

The Applicant, individuals, and organisations making submissions on this Application will be notified at each stage of the Application. If the Board approves a variation to the Code, that decision will be notified to the Forum. If a request to review the decision is not made by the Forum, the variation will be gazetted and registered as a legislative instrument. Stakeholders (including the Applicant) and submitters will be advised of the notification and gazettal in the national press and on the FSANZ website.

10. Consultation

10.1 Issues raised in submissions to the 1st Assessment Report

FSANZ sought comment from the public and interested stakeholders on the 1st Assessment Report between 20 September and 1 November 2011. Nine submissions were received of which 6 submitters supported further progression of the Application, two did not support the Application and one did not make their position known. The nine submissions were split between four jurisdictions which enforce the requirements of the Code, four industry groups or companies and one individual from an educational facility.

A number of the submitters raised specific issues they asked FSANZ to address during further consideration of the Application. The issues raised the name of the submitter and FSANZ's summary responses are provided in Table 2.

10.2 Submissions sought on this 2nd Assessment Report

FSANZ is now seeking further comment from the public and other interested stakeholders on the proposed draft variations to the Code to assist in completing its consideration of this Application.

FSANZ seeks comments about the scientific aspects of the Application as well as the proposed draft variations to the Code. In particular FSANZ is seeking submitters' views on the following questions:

- Do submitters agree with FSANZ's proposed draft variations to the Code providing permissions to use P100 as a processing aid using GMP principles for the proposed lists of food categories?
- Do submitters agree that the existing definition of RTE food in Standard 3.2.2 is appropriate for this permission?
- Are there other solid, RTE food categories which should be included in the list? Submitters should provide justification for any request to extend this list.

Following this second round of consultation, the FSANZ will consider submissions and make a final decision.

10.3 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), either Australia or New Zealand are obligated to notify WTO member nations when proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

There are no relevant international standards directly applicable to the use of P100 in food. Amending the Code to allow P100 as a processing aid to control *L. monocytogenes* on solid RTE foods is unlikely to have a significant effect on international trade as it is proposed for use as an additional technology, thereby providing for a choice for use by food manufacturers.

For this reason notification will not be made to the agencies responsible in accordance with Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade (TBT) or Sanitary and Phytosanitary Measures (SPS) Agreements.

Table 2: Summary of issues raised in submissions

Issue	Raised by	FSANZ response
Assurance of efficacy and prevention of resistance development (reduced sensitivity)		
Resistance development of <i>L. monocytogenes</i> to P100 and how this is assessed, monitored and prevented.	Queensland Health Ministry of Agriculture and Forestry, New Zealand	<ul style="list-style-type: none"> • This has been addressed in a new section, Section 5.2.2, as well as Section 6.3 of the report with more detail supplied in Section 5.3 of SD1. • Self-regulation is likely to be effective in ensuring resistance development does not occur since it is in the interest of both parties to ensure efficacy. The Applicant advised that they work closely with food processors to monitor P100 efficacy used standardised methodology and to check for lack of sensitivity. The Applicant provides SOPs to the industry on appropriate treatment methods and precautionary instructions such as product disposal, to reduce the possible occurrence of reduced susceptibility of <i>L. monocytogenes</i> to P100. The Applicant indicated that this issue has not been observed by long-term customers using P100 to date.
Technological function		
More information or explanation that P100 performs its technological function as a processing aid and not as a food additive.	Queensland Health Ministry of Agriculture and Forestry, New Zealand	FSANZ has expanded on the justification and arguments why it believes P100 functions as a processing aid for the proposed purpose for treating solid RTE food (Sections 5.2.1 and 6.1 and the Executive Summary).

Issue	Raised by	FSANZ response
<p>P100 functions as a food additive and not as a processing aid. If recontamination with <i>L. monocytogenes</i> occurs, then the phages will recommence activity and hence function, so P100 has an ongoing function.</p>	<p>Food Technology Association of Australia</p>	<p>FSANZ concludes that P100 does not have any ongoing technological function to act as an anti-microbial agent, and it is unable to attack re-introduced <i>L. monocytogenes</i> (ie recontamination after P100 treatment) in solid RTE foods. This is because the phage particles are bound to the surface of the food and are not mobile so are unable to locate <i>L. monocytogenes</i> that may re-contaminate food. This is explained in Section 5.4 of SD1 and summarised in Sections 5.2.1 and 6.1 of the report. It is also explained in reference Guenther et al, 2009, and analysis of data undertaken by FSANZ</p>
<p>Will P100 be incorporated into the treated food, such as cheese, or will it only be used to treat the surface of the final food, either by dipping or spraying?</p>	<p>Queensland Health</p>	<p>The Application is for the surface treatment of food only, so the report and proposed drafting now make this clear.</p>
<p>Is P100 specific against other strains of <i>Listeria</i> other than <i>monocytogenes</i>?</p>	<p>Food Technology Association of Australia</p>	<p>P100 is effective against other species of <i>Listeria</i> (such as <i>L. innocua</i>).</p>
<p>Specification</p>		
<p>Additional specification criteria suggestions:</p> <ul style="list-style-type: none"> • It is free of indicator organisms such as <i>E. coli</i>, and common food-borne pathogens such as <i>Salmonella spp.</i>, <i>Staphylococcus aureus</i> • Specific number of viable phages/mL • Other physical properties. 	<p>Queensland Health</p>	<ul style="list-style-type: none"> • FSANZ's view is that manufacture under GMP is sufficient to ensure microbiological safety of the P100 product, as discussed in Section 6.6 of the report. • FSANZ does not consider it necessary to define what the concentration of the P100 preparation should be, either as the commercial concentrated form or the diluted solution used to treat food. This information will be provided by the P100 supplier to the end user, and the use concentration will be a commercial decision by the end user determined by GMP. • FSANZ does not consider it is necessary to provide physical properties in regulatory specifications.

Issue	Raised by	FSANZ response
<p>Queried how the P100 preparation can be amended to address any reduced efficacy but still be consistent with the specification based on two statements in the 1st Assessment Report: “the Applicant has also advised that they will continuously work with users to monitor phage resistance development and to update the P100 preparation as required to maintain efficacy.” and “The P100 bacteriophage species could be updated as necessary, to maintain efficacy, while conforming to the specification.”</p> <p>Would the Applicant need to initiate a new Application if the specification was amended or the P100 preparation changed to maintain specificity against <i>L. monocytogenes</i>.</p>	<p>Ministry of Agriculture and Forestry, New Zealand Food Technology Association of Australia New South Wales Food Authority</p>	<ul style="list-style-type: none"> • FSANZ notes this concern by a number of submitters to these statements made in the report and consulted further with the Applicant. These statements have been deleted or amended. The P100 preparation contains the phage P100, not a cocktail of different phage species. Other preparations of P100, providing they continued to meet the specifications, would be considered to be efficacious for the stated purpose, subject to ongoing determination of efficacy by the manufacturer. Section 5.2.2 deals with assessing efficacy and how the Applicant would deal with reduced sensitivity if any, of <i>L. monocytogenes</i> to P100. • The Applicant performs checks on the identity of their P100 preparations and performance regularly to ensure it has not changed. • Section 6.5 addresses the specification. • Mutations to the phage genomic structure that could make it no longer compliant with the P100 taxonomic specification would require an approval of this new phage preparation by a new Application.
<p>Analytical methods</p>		
<p>Analytical issues: availability of appropriate analytical methods, utility in different food matrices, environmental swabs for the phage. Use of P100 may cause analytical problems for checking for <i>L. monocytogenes</i> contamination of food. It notes these, and other questions, will need to be considered by the proposed Implementation Sub Committee (ISC) advisory group on analytical methods.</p>	<p>Queensland Health</p>	<ul style="list-style-type: none"> • FSANZ notes the comments and agrees these are matters best addressed by the proposed new Expert Advisory Group for analytical methods to be set up by ISC. • FSANZ has addressed analytical methods in Section 6.4 of this report which is taken from Section 4.5 of SD1. Both plate count and PCR methods are suitable for determining and confirming the presence of P100 on treated food. The primers are specific to P100. The Applicant has methods and expertise that it can provide to the food industry and also enforcement agencies.

Issue	Raised by	FSANZ response
Labelling		
Not requiring treated food to be labelled because P100 treatment has been concluded to function as a processing aid will deceive consumers	Food Technology Association of Australia	The response to this enquiry is provided in the expanded Section 6.3 (Labelling implications) of the report.
Recommendation 28 of the recent <i>Labelling Law and Policy Review</i> report recommends that new technologies be labelled for 30 years from their introduction. The use of a live organism is unprecedented as processing aids and there may be consumer expectations that phage treated food will be labelled.	South Australia Health	FSANZ notes this comment. The whole of government view of the Labelling Law and Policy Review did not support this recommendation, and agreed instead that FSANZ continue to apply a case-by-case approach to the labelling requirements for new technologies. The Forum also agreed to develop a Ministerial Policy Guideline for the case-by-case consideration of regulatory (i.e. labelling) and non-regulatory measures applying to food produced using a new technology requiring a pre-market safety assessment. FSANZ's assessment on labelling of treated food is provided in Section 6.3 of the report.
Other issues		
Data on the stability of P100 during storage and on the treated food products is required.	Ministry of Agriculture and Forestry, New Zealand	The Applicant provided information on the stability of the P100 concentrate, which is detailed in Section 4.5 of SD1. P100 is stable at the storage temperature of 2-8°C for six months. The various studies reported on efficacy and performance of P100 and comparable phage preparations (SD1) also reported on stability of activity and ongoing functionality of the phage on treated solid food. P100 is functional for 6-24 hours after treatment. The phage either becomes inactivated or bound to the surface of food after this time.
Bacteriophage control agent is listed as a sub-class of the preservative class in Schedule 5 of Standard 1.3.1. Does this need to be reviewed?	Ministry of Agriculture and Forestry, New Zealand	FSANZ does not see a need to review this entry. This is because substances can be either a food additive or processing aid depending on how they perform their technological function in the treated food. See sub-clause 3 (b) of Standard 1.3.3. This situation applies to chemical substances as well as for bacteriophage preparations.

Issue	Raised by	FSANZ response
Believes the Applicant should hold discussions with the NZ Environmental Protection Authority (EPA, formerly ERMA) as P100 may be considered as a new organism for import permission. Similarly they may need to consult with MAF Biosecurity, to assess if there are any biosecurity implications (with importing P100 to NZ).	Ministry of Agriculture and Forestry, New Zealand	FSANZ notes these points, and suggest they are outside FSANZ's direct area of responsibility for the current assessment and has suggested to the Applicant that they initiate discussions with the relevant authorities.
Is there any potential for the use of phages for medical treatment and if there is, what provisions are made to ensure there are no health implications from approving their use in food.	South Australia Health	FSANZ is not aware of any current or proposed medical use of P100. It is understood that the use of P100 to treat food would not have any detrimental medical effect.
No need to approve P100 when ozone can be used to achieve the same outcome, without the need to approve a new microbiological agent, being phages.	FreshBins Pty Ltd	FSANZ notes this submission, but it considers there are no issues to address as it is assessing the Application to permit P100, not to assess the use of ozone or even to compare P100 with ozone. If P100 is permitted then it will be an alternative treatment food companies can use along with other technologies to ensure safety of the final processed food. Food companies will make commercial decisions on what treatment they use to treat their food, based on a variety of parameters. Ozone already has specific permissions as a processing aid in the Tables to clause 11 and 12 of Standard 1.3.3.
Suggest the term P100 should always be used in the reports and not 'a bacteriophage preparation' or 'the bacteriophage preparation' to make the statements specifically about the focus of the assessment.	Ministry of Agriculture and Forestry, New Zealand	FSANZ agrees with this comment. The reports have been amended so that comments that are about the specific preparation of the Application are referred to as P100. In some cases reference to bacteriophage preparations has been retained as they are general statements.

Issue	Raised by	FSANZ response
Supports the Application	<p>B.-d. Farm Paris Creek Pty. Ltd.</p> <p>Individual from The Gordon TAFE</p> <p>Hawkins Watts Limited (represents the Applicant in the NZ market)</p>	No issues
How does FSANZ propose to address solid RTE foods where liquid may occur in the pack (eg deli meats with exudate/purge/cook-out liquid)?	New South Wales Food Authority	<p>This issue has been picked up in the drafting, where solid RTE foods visibly covered or immersed in a liquid phase are not covered by the proposed permission to treat with P100.</p> <p>There are no safety issues with using P100 to treat such foods but the technological function is as a food additive and not as a processing aid, since phage particles have an ongoing function in the liquid phase, and are not all likely to be bound to the solid food surface.</p>
If the Applicant, or other company, wants to use P100 (or other phage preparation) to treat liquid foods it would be classified as a food additive and so require labelling. This has the potential to cause confusion for the food industry and consumers, since labelling would depend on the phase of the treated food.	New South Wales Food Authority	<p>FSANZ notes and agrees with this comment. The Applicant has indicated that it does not seek permission to treat liquid food with P100. However, a new Applicant could seek permission for another phage preparation to treat liquid foods. It is likely an assessment would indicate the phage preparation functions as a food additive and so labelling would be required.</p>

Issue	Raised by	FSANZ response
<p>Concern that public health professionals working for jurisdictions such as environmental health officers, food safety auditors and microbiologists need to be advised of any relevant issues for them if this product is approved. Issues noted are:</p> <ul style="list-style-type: none"> • resistance development and how this may be reduced • issues related to food safety programs and auditing • new control points and corrective actions • efficacy assessment of treatment • P100 treated food handled differently • contamination of P100 treatment solution • analytical testing methodology • additional precautions to minimise cross contamination in labs. 	<p>Queensland Health</p>	<p>FSANZ notes these points. If P100 is approved it may be appropriate to provide more detailed technical information on FSANZ's website. This would aim to assist jurisdiction officers and food industry stakeholders.</p>

PRIMARY LEGISLATIVE OBJECTIVES

11. Addressing FSANZ's Objectives for Standards setting

FSANZ is required by its legislation to meet the section 18 objectives of the FSANZ Act when it is developing or varying a food standard as noted in Section 3 of this report.

FSANZ considers the main objective which applies to this Application is the primary objective of protection of public health and safety. The other two primary objectives are considered of less direct importance. How FSANZ has addressed these objectives during the consideration of this Application is noted below.

11.1 Protection of public health and safety

FSANZ's risk assessment concludes that approving the use of P100 to treat solid RTE foods does not present any public health and safety risks.

11.2 Providing adequate information for consumers to make informed choices

P100 has been determined to perform its technological function as a processing aid when used to treat solid RTE foods. Processing aids are exempted from labelling requirements on package foods due to subclause 3(d) of Standard 1.2.4. FSANZ does not believe there are any appropriate reasons to exclude the labelling exemption for P100.

11.3 Prevention of misleading and deceptive conduct

FSANZ has considered this objective and concludes there are no misleading or deceptive conduct aspects to this assessment.

11.4 Subsection 18(2) considerations

FSANZ had regard to the matters set out in subclause 18(2) of the FSANZ Act as noted in Section 3 of the report. Importantly, FSANZ is required to have regard to the Policy Guidelines of the Forum relevant to the Application. For this Application it is the Policy Guideline: *Addition to Food of Substances other than Vitamins and Minerals*. Since the purpose for use of P100 is as a processing aid, consideration falls under 'Technological Function'. FSANZ has therefore considered the Application under the five specific policy principles noted in Section 3.

The Application has provided a clear stated purpose, being the technological function that P100 performs to reduce the concentration of *L. monocytogenes* on the surfaces of treated solid RTE food. The risk assessment has concluded that use of P100 to treat food is safe for human consumption and that the amounts added in the proposed quantity and forms are consistent with delivering the stated purpose. The Applicant does not wish to make any nutrition, health or related claims related to the use of P100 to treat food.

CONCLUSION

12. Conclusion and Preferred Approach

This Application has been assessed against the requirements of section 29 of the FSANZ Act, including the Policy Guideline of the Forum relevant to this Application.

FSANZ concluded that P100 is technologically justified as a processing aid for the purpose of reducing *L. monocytogenes* levels on specific solid RTE foods. There was no ongoing technological function performed by P100 on treated solid RTE foods. The use of P100 for this purpose does not pose any public health and safety risks.

The Policy Guidelines of the Forum relevant for this Application have been addressed in this assessment. The technological function (the stated purpose) of using P100 as a processing aid has been articulated and has been assessed as being met. The assessment has concluded that use of P100 as proposed by the Applicant is both safe and suitable.

The proposed draft variations are provided in **Attachment 1**.

Preferred Approach

To prepare a draft variation to the Table to clause 14 of Standard 1.3.3 – Processing Aids to add *Listeria* phage P100 as an approved processing aid for the surface treatment of solid ready-to eat meat and meat products (including poultry), fish and fish products, fruit and fruit products, vegetables and vegetable products and cheese.

To prepare a draft variation to Standard 1.3.4 – Identity and Purity to include a specification for P100 in the Schedule.

Reasons for Preferred Approach

The preparation of a draft amendment to the Code approving the use of P100 as a processing aid in Australia and New Zealand is proposed for the following reasons:

- the safety assessment did not identify any public health and safety concerns
- the assessment concluded that for the purpose proposed by the Applicant, P100 has a technological function as a processing aid in solid RTE foods. It has no ongoing technological function in these foods
- the assessment also concluded that P100 is likely to have an ongoing technological function in liquids and therefore to exclude liquid and semi-solid foods and solid ready-to-eat foods covered in a liquid from this permission
- approval for use of P100 as a processing aid is consistent with the Policy Guidelines of the Forum on the *Addition to Food of Substances other than Vitamins and Minerals*
- there are no other measures that would be more cost-effective than a variation to Standard 1.3.3 that could achieve the same end.

13. Implementation

If the proposed draft variations are approved, they will come into effect on gazettal.

References

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ATTACHMENTS

1. Draft variation to the *Australia New Zealand Food Standards Code*
2. Draft Explanatory Statement

Attachment 1

Draft Variations to the *Australia New Zealand Food Standards Code*



Food Standards (Application A1045 – Bacteriophage Preparation P100 as a Processing Aid) Variation

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The Standard commences on the date specified in clause 3 of this variation.

Dated XXXX

Standards Management Officer
Delegate of the Board of Food Standards Australia New Zealand

1 Name

This instrument is the *Food Standards (Application A1045 – Bacteriophage Preparation P100 as a Processing Aid) Variation*

2 Variation to Standards in the Australia New Zealand Food Standards Code

The Schedule varies the Standards in the *Australia New Zealand Food Standards Code*.

3 Commencement

These variations commence on **the date of gazettal**.

SCHEDULE

[1] **Standard 1.1.1** is varied by inserting in alphabetical order in clause 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.

[2] **Standard 3.2.2** is varied by deleting the following in clause 1 –

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] **Standard 1.3.3** is varied by inserting in alphabetical order in the Table to clause 14 –

<i>Listeria</i> phage P100	Antilisterial treatment for use on the surface of the following ready-to-eat foods– (a) meat and meat products; (b) fish and fish products; (c) fruit and fruit products; (d) vegetables and vegetable products; (e) cheese; if the foods are solid, and not wholly or partly covered in a liquid.	GMP
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Editorial Note:

Meat is defined in clause 1 of Standard 2.2.1.

Foods that are solid hold their shape and do not flow when placed on a flat surface such as a table. An example of a solid food is a cut melon. Fruit purée, on the other hand, would not be considered a solid food.

[4] **Standard 1.3.4** is varied by inserting in the Schedule—

Specification for *Listeria* phage P100

Biological classification

Order
Family

Caudoviridae
Myoviridae

Subfamily
Genus
Species
GenBank Accession Number

Spounaviridae
Twort-like
Listeria phage P100
DQ004855

Draft Explanatory Statement

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).`

Division 1 of Part 3 of the FSANZ Act specifies that the Authority may accept applications for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering an application for the development or variation of food regulatory measures.

FSANZ accepted Application A1045 which seeks to approve the use of the bacteriophage preparation P100 (referred to as *Listeria* phage P100) as a processing aid to reduce the concentration of *L. monocytogenes* on solid ready-to-eat foods. The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft variation.

2. Purpose and operation

Currently there is no permission for using the bacteriophage preparation P100 as a processing aid to reduce the concentration of *L. monocytogenes* on solid ready-to-eat foods. The draft variation is proposed to address this by permitting the use of *Listeria* phage P100 as a processing aid to treat specific ready-to-eat foods (meat and meat products, fish and fish products, fruit and fruit products, vegetables and vegetable products and cheese) under conditions of Good Manufacturing Practice.

The draft variation will also insert a specification for *Listeria* phage P100 into the Schedule to Standard 1.3.4.

3. Documents incorporated by reference

The variation does not incorporate any documents by reference.

4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration to date of Application A1054 has included a round of public consultation following an assessment and the release of an associated report. Submissions were called for on 20 September 2011 for a six-week consultation period.

A Regulation Impact Statement (RIS) was not required because the proposed variations to are likely to have a minor impact on business and individuals and is not required for applications relating to processing aids as they are minor or machinery in nature and their use would be voluntary.

5. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the FSANZ Act.

6. Variations

Item [1] inserts the definition of ready-to-eat food, as it appears in clause 1 of Standard 3.2.2, into clause 2 of Standard 1.1.1. The definition currently applies only to Standard 3.2.2, but will apply to the whole Code once the variation commences.

Item [2] removes the definition of ready-to-eat food from clause 1 of Standard 3.2.2 as the definition will appear in Standard 1.1.1 instead.

Item [3] inserts an entry for Listeria phage into the Table to clause 14 of Standard 1.3.3 to permit the use of Listeria phage P100 as a processing aid to treat specified solid ready-to-eat foods (meat and meat products, fish and fish products, fruit and fruit products, vegetables and vegetable products and cheese).

The permission does not apply to solid RTE foods that are wholly or partly covered in liquid.

Item [4] inserts a specification for Listeria phage P100 into the Schedule to Standard 1.3.4.