

20 September 2011
[17-11]

APPLICATION A1045

BACTERIOPHAGE PREPARATION P100 AS A

PROCESSING AID

1st ASSESSMENT REPORT

Executive Summary

Purpose

FSANZ received an Application from EBI Food Safety Ltd to amend the *Australia New Zealand Food Standards Code* (the Code) to permit the use of a bacteriophage (phage) preparation Listex P100 (designated P100 preparation) as a processing aid to reduce numbers of *Listeria monocytogenes* in non-liquid ready-to-eat foods. It is proposed that the bacteriophage preparation is applied to food as a spray or dip immediately prior to packaging.

Background

Bacteriophages infect, and destroy bacteria. They are highly specific and do not infect bacteria other than the species they infect. They are unable to infect plant, animal or human cells and are the most abundant biological entities on earth – being present wherever bacteria exist.

The Applicant proposes the use of P100 as a technology to be used in combination with other listericidal techniques currently applied in food processing. It is designed to complement good hygienic practices (GHP) used in food manufacturing. It is not meant for use as a surfactant, disinfectant or a general bactericide intended for other purposes within the processing facility. Phages used to treat food should be both lytic¹ and non-transducing² to ensure food safety.

Ready-to-eat foods are defined as any foods which are normally eaten in its raw state or any food handled, processed, mixed, cooked, or otherwise prepared into a form which is normally eaten without further preparation. Ready-to-eat non-liquid products may be treated with this preparation. FSANZ has confirmed with the Applicant that liquid foods are excluded from the scope of this Application.

¹ Bacteriophages that undergo replication within the bacterial hosts to release phage particles by rupturing the host cells without integrating into the bacterial chromosome

² Transduction is the mechanism whereby bacterial genetic material is transferred between bacteria through a bacteriophage vector.

FSANZ has assessed the safety and the proposed technological function of the P100 preparation. In doing so, the efficacy and the continuity of the technological function under proposed use has been assessed. FSANZ has concluded that the P100 preparation is safe, effective and has no ongoing technological function when used under commercial conditions in non-liquid ready-to-eat foods

The Application is being assessed under the Major procedure and will include two rounds of public consultation.

Risk Assessment

FSANZ has assessed the scientific evidence submitted by the Applicant and other peer-reviewed scientific information. FSANZ has concluded that the bacteriophage preparation poses no risk to public health and safety for Australian or New Zealand consumers.

The stated purpose for this bacteriophage preparation is to reduce or eliminate *L. monocytogenes* in a range of ready-to-eat foods. The evidence presented to support this use provides adequate assurance that the bacteriophage preparation, in the form and amounts added is technologically justified and has been demonstrated to be effective in achieving its stated purpose.

Furthermore, the weight of evidence, coupled with the restricted functionality of the bacteriophage in commercial conditions and in non-liquid food matrices, supports the conclusion that P100 has no ongoing technological function in non-liquid ready-to-eat food according to the use and levels proposed by the Applicant.

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 reviewed the information on the possibility of emergence of bacteriophage resistant mutants of *Listeria monocytogenes*. FSANZ concluded after considering the scientific evidence, backed by views of experts in the field, 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 this bacteriophage preparation.

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

Risk Management

P100 functions as a processing aid for the stated purpose when treating non-liquid foods so it is proposed to include permission for P100 within Standard 1.3.3 – Processing Aids. This would most likely be within the Table to clause 14 – Permitted processing aids with miscellaneous function. Because there are currently no specifications for P100 in the Code a new specification would need to be written 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.

Assessing the Application

In assessing the Application, FSANZ has 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 to permit P100 as a processing aid in non-liquid foods
- whether other measures would be more cost-effective than a variation to Standard 1.3.3 that could achieve the same end
- any relevant New Zealand standards
- any other relevant matters.

Preferred Approach

Proceed to development of a food regulatory measure to vary Standard 1.3.3 – Processing Aids to add P100 as an approved processing aid for the surface treatment of non-liquid ready-to-eat foods.

Reasons for Preferred Approach

The development of an amendment to the Code to give approval to use P100 as a processing aid in Australia and New Zealand is proposed on the basis of the available scientific evidence, 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 non-liquid ready-to-eat foods. It has no ongoing technological function in these foods.
- approval for use of P100 as a processing aid is consistent with Ministerial Council 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 end.

Consultation

Public submissions are now invited, in particular on:

- scientific aspects of the Application, in particular any information relevant to the safety and technological function assessment
- the appropriate requirements that should be contained in a specification for P100
- parties that might be affected by having this Application approved or rejected.

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](#). 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) 1 November 2011

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
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SUPPORTING DOCUMENT

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

INTRODUCTION

FSANZ received an Application from EBI Food Safety Ltd to amend the *Australia New Zealand Food Standards Code* (the Code) to permit the use of a bacteriophage preparation Listex P100 (called P100 preparation for the rest of the report) as a processing aid in ready-to-eat foods (RTE). FSANZ confirmed with the Applicant that the request was specifically for non-liquid ready-to-eat foods. The bacteriophage preparation was proposed for use to reduce numbers of *Listeria monocytogenes* in foods. The Applicant claims P100 acts as a processing aid in ready-to-eat foods, and so requested that Standard 1.3.3 – Processing Aids be amended.

L. monocytogenes is a well-known foodborne pathogen, and can be a contaminant of raw and RTE food products such as poultry, seafood and dairy products. Currently, the Code permits no tolerance of *L. monocytogenes* in several ready-to-eat foods. During the past 10 years, 48% of food recalls carried out in Australia for microbial contamination has been due to *L. monocytogenes* (FSANZ 2011).

Bacteriophages are specific to the strains of bacteria they infect and are not pathogenic to plants, animals or humans. They are the most abundant biological entities on earth and occur everywhere in the environment.

It is important to ensure food safety that phages used to treat food are both lytic³ and non-transducing⁴. This is to ensure there is no transfer of genes (or DNA) between host bacteria.

Phage-related research and application began in Europe and USA in the 1880s, but soon declined with the advent of antibiotics. However, clinical use and research were maintained in Eastern European countries. The application of bacteriophages for various uses has recently become increasingly important due to concerns about antimicrobial resistance development in pathogenic microorganisms. Greater accessibility to Eastern European research has resulted in an increase in bacteriophage-related knowledge development during the last decade and much more is now known about their biology.

Bacteriophage-based products are being produced and used in the Netherlands, US and Georgia for a range of applications. Food-related use has been fairly recent and more products are being researched and developed. The use of the P100 preparation and others to treat food has been approved by US, Canada and The Netherlands.

1. The Issue / Problem

The Applicant has requested that the P100 preparation be approved as a processing aid to reduce levels of *L. monocytogenes* in ready-to-eat food. A pre-market assessment is required before any new processing aid is permitted to be used to process food sold in Australia and New Zealand.

There is currently no permission for the use of bacteriophages preparations as processing aids in the Code. 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 safety of the P100 preparation and of using it to treat food, as well as an assessment of the technological function of P100 for its proposed use.

³ Bacteriophages that undergo replication within the bacterial hosts to release phage particles by rupturing the host cells without integrating with the bacterial chromosome

⁴ Transduction is the mechanism whereby bacterial genetic material is transferred between bacteria through a bacteriophage vector.

The assessment also considers whether it functions as a processing aid (no extended technological function in the final food) or as a food additive (having a technological function in the final food).

2. Current Standard

2.1 Background

All new processing aids must undergo a pre-market assessment before they can be permitted to treat food. The following definitions in the Code have been used for this assessment.

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.

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 FDA in 2006 for use as a processing aid in cheese and in 2007, extended its use to all food products susceptible to *Listeria monocytogenes*. Ingredient labelling requirements were initially specified for bacteriophage 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 ready-to-eat 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 the P100 preparation 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 bacteriophage as a processing aid to reduce *L. monocytogenes* in foods. 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 Ministerial Council 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.

This objective has been considered by conducting a risk assessment. This risk assessment has also investigated the technological function and justification for using the phage P100 preparation, to address the Ministerial Council Policy Guideline: *Addition to Food of Substances other than Vitamins and Minerals*.

4. Questions to be answered

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

- Is the P100 bacteriophage preparation suitably well characterised?
- Does the P100 preparation 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 the P100 preparation ineffectual?
- Does the P100 preparation present any food safety issues?
 - Are there potential allergens present in the P100 preparation?
 - 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.

5. Risk Assessment Summary

5.1 Characterisation

5.1.1 Is the P100 bacteriophage preparation suitably well characterised?

The Applicant has provided information detailing the identity of the P100 bacteriophage as belonging to the Order *Caudovirales*, Family *Myoviridae* and Group SPO-1. The host (production) organism is a non-pathogenic type strain of *Listeria innocua* (ATCC 33090, DSM 20649, NCTC 11288, SLCC 3379). The bacteriophage P100 and production organism are completely characterised.

5.2 Technological function

5.2.1 Does the P100 preparation achieve its stated technological purpose?

FSANZ has made an assessment of the efficacy and the possibility of an ongoing technological function when the P100 preparation is used for the stated purpose. The P100 is effective in reducing numbers of *L. monocytogenes* in treated foods.

The overall weight of evidence, noting the restricted functionality of the bacteriophage in commercial conditions and in non-liquid food matrices, supports the conclusion that P100 has no ongoing technological function in non-liquid ready-to-eat food according to the use and levels proposed by the Applicant.

It is important to note that P100 cannot be assumed to be a complete single treatment that will destroy and eliminate all *L. monocytogenes* from treated food. It should be considered only as additional technology food manufacturers can use along with their current processes to control *L. monocytogenes*. Food manufacturers will need to determine appropriate process optimisation and SOP's (Standard Operating Practices) to establish efficacy on a case-by-case basis for different foods and different production plants and to monitor efficacy consistently.

The risk assessment reviewed the information on the possibility of emergence of bacteriophage-resistant strains of *L. monocytogenes*. The conclusion from the scientific evidence, supported by experts in the field and international regulators, is that when using bacteriophages to treat food, is that 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 needs to 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, is being maintained by the Applicant. The P100 bacteriophage species could be updated as necessary, to maintain efficacy, while conforming to the specification.

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 is supported by the absence of biologically significant homology between the P100 proteins and any known allergens or toxins.

P100 bacteriophage is only effective against bacteria of the genus *Listeria*. It cannot infect plant, animal or human cells. Ingestion or contact with P100 does not present a public health risk.

5.4 Conclusion

The findings of the risk assessment for Application A1045 show that the use of the P100 preparation is completely characterised and it is technologically justified and safe for use in non-liquid ready-to-eat foods as proposed by the Applicant. There is no ongoing technological function performed by the P100 preparation in non-liquid ready-to-eat foods.

RISK MANAGEMENT

6 Risk Management Issues

The risk assessment conclusions from Section 5.4 are that the use of P100 is technologically justified and is safe for use in non-liquid ready-to-eat foods. FSANZ has a number of regulatory risk management matters to address these risk assessment conclusions. These matters are considered in the following sections.

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 ready-to-eat food products for human consumption.

FSANZ assessed how the phage preparations performed their technological function; i.e. during processing only (therefore as a processing aid) or in the final food (food additive) (see Section 2.1). Section 5.2.3 of SD1 concludes that P100 performs its technological function during the processing and manufacture of food and has no ongoing technological function in non-liquid final 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 a functionality to seek, locate and destroy bacteria. It is concluded from the studies that the phages are 'bound' to the food surfaces and have limited mobility in non-liquid foods to locate and destroy remaining *L. monocytogenes* and therefore have no ongoing functionality.

The situation is different for liquid foods (which are not being assessed in this Application). This is explained by the hypothesis that phages have greater diffusion in liquid media and so a greater likelihood to locate and destroy bacteria than when bound or less mobile on solid media.

FSANZ concludes that the P100 preparation acts as a processing aid in non-liquid ready-to-eat 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 Assessment Report, FSANZ concludes that it is appropriate to permit P100 as a processing aid to treat non-liquid ready-to-eat food and it therefore proposes to amend Standard 1.3.3.

FSANZ has not concluded at this stage what the permission should encompass. This will be considered further following public comment on this Report (in particular FSANZ seeks comments on the questions noted in Section 10 – Consultation). It is possible that P100 could be used under conditions of Good Manufacturing Practices (GMP) in appropriate processed foods and during the processing of these foods. That is, the substance could be added to the Table to clause 14 – Permitted processing aids with miscellaneous function in Standard 1.3.3. P100 could be permitted as a processing aid for non-liquid ready-to-eat foods.

Permitting P100 as a processing aid means that food manufacturers could use it as a

technology in the concentrations and method recommended by the manufacturer.

Food manufacturers may also need to use other technologies that are available to control *L. monocytogenes* in foods and food processing (e.g. as part of their HACCP program). As with all new processes or technologies, manufacturers will need to consider their specific products and process requirements and conduct trials before use of the P100 preparation. In particular, P100 concentrations and contact time required to reduce bacterial levels should be determined.

The Applicant has advised that the manufacturers will be provided with clear instructions on the use of the P100 preparation as part of an ongoing assurance program to limit phage resistance developing in food production facilities.

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. The specification will provide for ensuring the ongoing efficacy of the P100 preparation.

6.3 Labelling implications

The Applicant sought approval for the use of P100 as a processing aid. Under paragraph 3(d) of Standard 1.2.4 – Labelling of Ingredients, processing aids are exempt from ingredient labelling. Based on the evidence submitted by the Applicant, as well as information from other scientific information, FSANZ concludes that the P100 preparation achieves the technological function (control of *L. monocytogenes*) as a processing aid in non-liquid foods. Ingredient listing for P100 is therefore not required.

6.4 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.

A standard agar overlay method can be employed. 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 which is determined by this plaque assay.

The Application contains information relating to a Polymerase Chain Reaction (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'-ccttcacgcatcttggtagag (binds P100 genome bp: 108867-108888); reverse: 5'-cagggttgatttaggtactc (binds P100 genome bp: 109957-109937). This analytical method is available and could be used by analytical laboratories for enforcement purposes if required.

6.5 Specification for P100 bacteriophage preparation

There are currently no specifications for bacteriophages, or more 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. A draft 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 bacteriophage preparations though similar, but non-identical phage preparations such as A511 would not be permitted. The specification would permit phage manufacturers to modify the P100 preparation to ensure efficacy as *L. monocytogenes* may adapt and alter with time.

Biological classification and microbiological properties for the P100 preparation are listed in Table 1.

Table 1: Recommended specifications for P100 bacteriophage preparation

<i>Biological classification</i>	
Order	Caudovirales
Family	Myoviridae
Group	SPO-1
Species	P100
<i>Microbiological properties</i>	<i>Limit</i>
<i>Listeria</i> spp.	Negative in 25 mL

FSANZ seeks assistance from relevant stakeholders as to what other requirements should be incorporated into a P100 specific specification to ensure food safety.

6.6 Addressing the FSANZ objectives

The legislative objectives that FSANZ is required to meet when developing or varying a food standard are detailed in Section 3. 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.

6.6.1 Risk to public health and safety

FSANZ’s risk assessment concludes that approving the use of the P100 bacteriophage preparation to treat non-liquid ready-to-eat foods does not present any public health and safety risks.

6.6.2 Providing adequate information for consumers to make informed choices

For this Application the P100 preparation has been determined to perform its technological function to treat non-liquid ready-to-eat food as a processing aid. 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 the P100 preparation, especially since there are unlikely to be any phage preparation remaining on treated food.

6.6.3 Prevention of misleading and deceptive conduct

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

6.7 Consistency with Policy Guidelines

As noted in Section 3, FSANZ is required to have regard to the Ministerial Council Policy Guidelines relevant to the Application, in this case being the Policy Guideline: *Addition to Food of Substances other than Vitamins and Minerals*. Since the purpose for use of the P100 preparation 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 when it is used as proposed to treat non-liquid ready-to eat 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.

7. Options

Two options are available for consideration by FSANZ at the next stage of the assessment of this Application. These are:

Option 1 Reject the Application

Option 2 Prepare a draft food regulatory measure

8. Impact Analysis

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 benefits and costs 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.

The Office of Best Practice Regulation (OBPR) in a letter dated 24 November 2010 (reference 12065) 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 machinery in nature.

8.1 Affected Parties

The affected parties for this Application may include:

- Sectors of the food manufacturing industry may wish to use P100 to reduce incidence of *L. monocytogenes* in 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 will be incurred in performing validation trials, advertising and marketing.

Manufacturers may need to manage consumer response to this new technology.

- Consumers may have access to a wider choice of ready-to-eat products which may be available for consumption.
- 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.

8.2 Benefit Cost Analysis

8.2.1 Option 1 – Reject the Application

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

There are no benefits to relevant stakeholders of this option.

8.2.2 Option 2 – Accept the Application and prepare a variation to Standard 1.3.3.

FSANZ notes that the permission of P100 as a processing aid is for application as an additional technology, not as a sole alternative to currently used procedures, to control levels of *L. monocytogenes*.

L. monocytogenes is a major food safety concern for ready-to-eat food as confirmed by FSANZ's most recent recall information. Recalls due to *L. monocytogenes* alone has 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 the P100 preparation is technologically justified and safe for use in non-liquid ready-to-eat 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.

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 and integration of this relatively new technology into their existing food regulatory framework.

8.3 Comparison of Options

Given that the acceptance of this Application imposes no significant financial burden (noting possible government costs) on any sector of the community; the use of this preparation raises no public health and safety issues, option 2 is the preferred option.

Communication and Consultation Strategy

9 Communication

As this is the first application FSANZ has assessed for the use of a bacteriophage preparation as processing aid to control a foodborne pathogen (*L. monocytogenes*) in food, an enhanced communication strategy will be employed.

Communication will include:

- a website fact sheet at the start of consultation
- a media release at the start of consultation.

Interested parties will also be notified about the availability of the assessment reports for public comment.

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

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 Ministerial Council. If a request to review the decision is not made by the Ministerial Council, 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

FSANZ is seeking comment from the public and other interested stakeholders to assist in the further consideration of this Application. As the Application is being assessed under the Major procedure, two rounds of public consultation will be held.

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

- Is there additional information relevant to the safety assessment of the use of P100 as a processing aid in manufacture of non-liquid ready-to-eat foods?
- Do submitters agree with FSANZ's conclusion that P100 functions as a processing aid for the Applicant's stated purpose to reduce concentrations of *L. monocytogenes* on non-liquid ready-to-eat foods?
- Do submitters agree with the proposed FSANZ specification for P100 provided in Section 6.5 and are there any additional processing and microbiological requirements needed to be added to the specification to ensure food safety?

Following the consultation on this 1st Assessment Report, if FSANZ prepares a draft variation to the Code, a second round of public comment on the draft variation will be held. The FSANZ Board will then consider the draft variation for approval.

10.1 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 the P100 preparation in food. Amending the Code to allow the P100 preparation as a processing aid to control *L. monocytogenes* in non-liquid foods is unlikely to have a significant effect on international trade as it is proposed for use as a technology, thereby providing for a choice for use by food manufacturers.

This matter will be considered at the next stage of the assessment and, if necessary, notification will be recommended 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. This will enable other WTO member countries to comment on proposed changes to standards where they may have a significant impact on them.

CONCLUSION

11. Conclusion and Preferred Approach

This Application has been assessed against the requirements of section 29 of the FSANZ Act.

FSANZ concludes that the P100 preparation is technologically justified as a processing aid for the purpose of reducing *Listeria monocytogenes* levels in non-liquid ready-to-eat foods. There is no ongoing technological function performed by the P100 preparation in treated non-liquid ready-to-eat foods. The use of the P100 preparation for this purpose does not pose any public health and safety risks.

The Ministerial Council Policy Guidelines 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.

Preferred Approach

Proceed to development of a food regulatory measure to vary Standard 1.3.3 – Processing Aids to add P100 as an approved processing aid for the surface treatment of non-liquid ready-to-eat foods.

Reasons for Preferred Approach

The development of an amendment to the Code to give approval to use P100 as a processing aid in Australia and New Zealand is proposed on the basis of the available scientific evidence, for the following reasons:

- the safety assessment did not identify any public health and safety concerns

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- the assessment concluded that for the purpose proposed by the Applicant, P100 has a technological function as a processing aid in non-liquid ready-to-eat foods. It has no ongoing technological function in these foods.
- approval for use of P100 as a processing aid is consistent with Ministerial Council 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 end.

References

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FSANZ (2001) Recall guidelines for packaged ready-to-eat foods found to contain *Listeria monocytogenes* at point of sale. FSANZ, Canberra, Australia.
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