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[18-12]

Approval Report – Application A1045

Bacteriophage Preparation P100 as Processing Aid

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Microcos B.V. (previously EBI Food Safety) to permit the use of a bacteriophage (*Listeria* phage) preparation Listex™ P100 as a processing aid.

On 20 November 2011, FSANZ completed a risk assessment and sought submissions on its assessment of the Application. Eight submissions were received. On 16 March 2012, FSANZ sought submissions on a draft variation. FSANZ received eight submissions.

FSANZ approved the draft Standard on 26 July 2012. The COAG Legislative and Governance Forum on Food Regulation¹ (Forum) was notified of FSANZ's decision on 2 August 2012.

This Report is provided pursuant to paragraph 33(1)(b) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

¹ Previously known as the Australia and New Zealand Food Regulation Ministerial Council

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Supporting documents

The following document used to prepare this Report is available on the FSANZ website at <http://www.foodstandards.gov.au/foodstandards/applications/applicationa1045bact4797.cfm>

- SD1 Risk Assessment Report
- SD2 Technical issues raised in submissions

1. Executive summary

Application A1045 was submitted by Microcos B.V. (previously EBI Food Safety) on 25 March 2010, seeking approval for including a bacteriophage (*Listeria* phage) preparation Listex™ P100 (subsequently called P100 in this report) as a processing aid under Standard 1.3.3 – Processing Aids, in the *Australia New Zealand Food Standards Code* (the Code). The purpose of using P100 as a processing aid was stated as being “to eradicate or decrease *Listeria monocytogenes* on various ready-to-eat (RTE)² food products for human consumption”. FSANZ clarified the Applicant’s request and narrowed it to treat certain solid RTE foods at risk of *L. monocytogenes* contamination, excluding liquid products.

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

Bacteriophages are the most abundant biological entities on earth and are present wherever bacteria exist. They infect specific strains of bacteria so the P100 bacteriophage would not infect any other bacteria except *Listeria* species (including *L. monocytogenes*). 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 without further preparation. Certain solid RTE products at risk of *L. monocytogenes* contamination may be treated with P100.

Analysis performed by FSANZ confirms that the use of P100, in the form and amounts proposed by the Applicant, is technologically justified and demonstrated to be effective in achieving its stated purpose and that it does not have an ongoing technological function when used with a range of solid RTE foods. The studies assessed to make this conclusion investigated the effects on solid RTE meat (including poultry) and meat products, fish and fish products, and fruits and vegetables and their products and cheese.

FSANZ also 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 ingestion of, or contact with, P100.

² There is an existing definition for RTE food in Standard 3.2.2: **ready-to-eat** food means food that is ordinarily consumed in the same state as that in which it is sold and does not include nuts in the shell and whole, raw fruits and vegetables that are intended for hulling, peeling or washing by the consumer.

2. Introduction

2.1 The Applicant

Micreos B.V. (previously EBI Food Safety) is a subsidiary of a privately owned company, Micreos Ltd, based in Wageningen, The Netherlands. It develops natural phage products against pathogenic bacteria in the food chain.

2.2 The Application

Application A1045 was made by EBI Food Safety on 25 March 2010, seeking approval for including a bacteriophage (*Listeria* phage) preparation Listex™ P100 (referred to as P100 in this Report) in Standard 1.3.3 – Processing Aids, in the *Australia New Zealand Food Standards Code* (the Code). The purpose of using P100 as a processing aid was stated as being “to decrease *Listeria monocytogenes* on various RTE food products for human consumption”. FSANZ clarified the Applicant’s request and narrowed its use to solid RTE foods at risk of *L. monocytogenes* contamination, and specifically excluding liquid products.

Bacteriophages are viruses that infect and break down bacterial cells. They do not infect animal or plant cells, and have therefore been considered safe for use in environmental, veterinary, agricultural, clinical and food-related applications. They are naturally abundant in saltwater, freshwater, soil, plants and animals (including people) and have been shown to be unavoidably present in foods.

Bacteriophages cannot actively locate bacterial cells, they are non-motile and rely on passive diffusion to locate and attach to receptor sites on target bacterial cells. In this application, bacteriophages are intended for use as an additional technology which is a final treatment to “mop up” any *L. monocytogenes* cells potentially remaining on the food surfaces after the product has been processed according to good hygienic practices and undergone listericidal processes during manufacture. The use of P100 is not intended as a replacement of good hygienic practices nor as an alternative to approved and effective cleaning and sanitising agents generally used in the food industry.

It is intended that food manufacturers would optimise and validate the use of P100 for each RTE food it is applied to, and its use would be integrated into existing food safety programs.

2.3 The current Standard

All new processing aids must undergo a pre-market assessment before they can be permitted for use in the manufacture of food. 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, was considered the

most applicable clause for P100.

2.4 Reasons for accepting the Application

The Application was accepted for assessment on the basis that:

- it complied with the procedural requirements under subsection 22(2)
- it related to a matter that warranted the variation of a food regulatory measure.

2.5 Procedure for assessment

The Application was assessed under the Major Procedure.

2.6 Decision

The draft variation as proposed following assessment was approved with amendments and is at Attachment A. An explanatory statement is at Attachment B.

The draft variation on which submissions were sought is at Attachment C.

3. Summary of the findings

3.1 Risk assessment

FSANZ considered the following risk assessment questions as part of the assessment for this Application, with the responses summarised below.

- 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?

The risk assessment of P100 is described in **Supporting Document 1 (SD1)** with the key elements summarised below.

3.1.1 Is P100 suitably well characterised?

The Applicant provided information detailing the identity of P100 as belonging to the Order *Caudovirales*, family *Myoviridae*, 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.

3.1.2 Does P100 achieve its stated technological purpose?

FSANZ assessed 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 such as A511). The specific solid RTE 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.

The conclusion of the efficacy studies on solid RTE food was that 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 (results represented by graph C in section 5.2.2 of SD1). Twelve out of 15 studies analysed by FSANZ showed this behaviour. Considering the results provided for a wide range of food products, the overall conclusion was that P100 does not have any ongoing technological function shortly after it has been applied to the surface of solid RTE foods. This is not the conclusion for P100 when used in liquids such as brine, where it may have an ongoing function.

FSANZ performed further analysis on extended storage time studies reported in more detail in section 2.2 of SD2, which provides additional support that P100 does not have an ongoing function.

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.

3.1.3 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 food manufacturers use Good Manufacturing Practice (GMP) and Good Hygienic Practices (GHP). This requires that 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 not dissimilar 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 unless they have been heat treated or undergone another comparable treatment to ensure phage inactivation. Adherence to GMP and 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, or appropriately treated before being reprocessed. Appropriate cleaning regimes are required to ensure there is no build-up of *Listeria* reservoirs in the facility. Continuous screening and monitoring of *Listeria* spp. for susceptibility to P100 is being maintained by the Applicant as technical assistance for users of P100.

The Applicant confirmed that the use of P100 will lower the amount of *Listeria* on treated foodstuffs (by a 1-3 log reduction) but it does not guarantee 100% elimination. The Applicant's customers occasionally encounter *Listeria* spp. despite the use of P100. While these may represent *Listeria* cells that were not killed by the phage application, it may also be indicative of a fault in the application, post processing contamination, or reflect the development of phage resistant bacteria.

FSANZ has been advised that whenever *Listeria* has been encountered by the Applicant's customers, these isolates are tested for phage sensitivity. It has been noted that some non-pathogenic *L. seeligeri* serovar 3 strains may be insensitive to P100 phage.

Apart from this, no phage-resistant isolates of *Listeria* spp. have been encountered to date by the applicant.

3.1.4 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 is 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.

3.1.5 Conclusion

Following the risk assessment FSANZ has 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 on solid RTE foods. This is not the situation when applied to liquids such as brine, where it may have an ongoing technological function. Semi-solid foods were not evaluated as no studies were available for assessment.

FSANZ has concluded that P100 is likely to maintain its efficacy (not develop reduced activity against *L. monocytogenes*) provided appropriate GMP and GHP are maintained by the food manufacturers. Ongoing assistance is also provided by the Applicant to food manufacturers who use P100 to continually check for the development of *L. monocytogenes* resistance to P100. To date such resistance development has not been found.

3.2 Risk management

FSANZ has concluded that P100 is safe and technologically justified for the intended purpose. FSANZ has considered the risk management matters relevant to the Application.

3.2.1 Technological function: processing aid or food additive?

This is an important regulatory issue related to the technological function performed by the Applicant's phage preparation. FSANZ assessed how P100 (and comparable phage preparations) performed their technological function i.e. whether it was effective during processing only (having no ongoing function in the final food, therefore considered a processing aid) or if the effectiveness continued in the final food (food additive) (see Section 3.1.2).

The risk assessment (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 on 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 to treat further 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. FSANZ has concluded that the phages may be 'bound' to the food surfaces and have limited mobility on solid foods to locate and destroy remaining *L. monocytogenes*, and therefore have no ongoing functionality.

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

3.2.2 Regulatory permissions

FSANZ has concluded that it was appropriate to permit P100 as a processing aid to treat specific solid RTE foods and it therefore amended Standard 1.3.3. Permission was granted to use P100, under conditions of 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. The specific food groups permitted are meat (including poultry) and meat products, fish and fish products, and fruits and vegetables and their products and cheese.

A new definition of "approved food for use of phage" has been included in Standard 1.3.3, incorporating the existing definition for RTE food in Chapter 3.2.2. Submitters questioned an earlier approach to relocate the definition for RTE food to Standard 1.1.1 – Preliminary Provisions – Application, Interpretation and General Prohibitions. They argued this would mean the definition would apply too broadly across the Code and that any unintended consequences would not have been fully evaluated. FSANZ agreed and for the purposes of this Application decided to limit the use of the definition to Standard 1.3.3 only.

FSANZ initially proposed that solid RTE foods fully or partially covered in a liquid were excluded from the permission. After further consideration and discussions with jurisdictional submitters, whose role is to ensure compliance with the Code, it was agreed that simplified drafting was more appropriate. Because the permission for using P100 for the proposed purpose is as a processing aid, then any use in foods where it had the potential to function as a food additive is not permitted. Therefore, simplified drafting was written stating only that specific types of solid foods can be treated with P100.

3.2.2.1 Overseas approvals

The European Food Safety Authority (EFSA) issued a scientific opinion in 2009 on the general 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).

EFSA subsequently released an opinion on the safety and efficacy of using P100 to treat raw fish (EFSA, 2012). This opinion was requested by the European Commission to evaluate an application dossier, submitted by the same Applicant (Mircleos B.V.), to treat raw fish with P100 to reduce *L. monocytogenes* contamination. Only two efficacy studies were considered as part of the analysis. EFSA raised a number of issues relating to ensuring efficacy of treatment in raw fish, but concluded that P100 should not present any human safety concerns.

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.

In 2006, P100 was granted Generally Recognized as Safe (GRAS) status by the United States Food and Drug Administration (USFDA) for use as a processing aid in cheese and in 2007, its use was extended 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, the 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 (Hazard Analysis and Critical Control Points) 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 – 10^9 pfu/g was also specified.

3.2.3 Risk management approaches to ensure efficacy

It is intended that food manufacturers optimise and validate the use of P100 for each RTE food it is applied to, and its use would be integrated into existing food safety programs.

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. This is discussed in detail in section 2.4 of SD2.

The requirement for food manufacturers to use GHP in 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. P100 is applied on the food surface in a controlled manner and is not meant for use as a disinfectant or general bactericide to treat surfaces and equipment within the food processing environment. Its use is purely to reduce the concentrations of *L. monocytogenes* that may contaminate the surfaces of food products that are processed and packed in the facility. It is therefore required that appropriate cleaning regimes are in place to prevent any build-up of *Listeria* reservoirs within the facility. Other GHP methods to reduce bacterial contamination of the equipment are also required, and are not replaced by the use of P100. All processes and practices adopted for validation, optimisation, monitoring and testing should be conducted as part of GMP.

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.

3.2.4 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.

One submitter requested that, given the unprecedented use of a 'live organism' as a processing aid, FSANZ should consider labelling. Another submitter noted that consumers may have concerns resulting from a lack of labelling information. Several other submitters noted P100 would be labelled if classified as a food additive, with one commenting that an exemption from labelling could be seen to deceive consumers.

In response to submitter comments, FSANZ considered whether P100 as a processing aid was a special case warranting ingredient labelling. While labelling is sometimes required for reasons of health and safety (for example, date marking or allergen labelling), this would not apply to P100 as it presents no health or safety issues.

Food is also labelled to provide adequate information to enable consumers to make informed choices. For example, ingredient labelling provides consumers with information on what ingredients (including food additives) have been added to the food. Processing aids, however, are not labelled as this information does not provide useful information for consumers. Rather, such labelling could be misleading or confusing as it would be difficult to declare the use of P100 preparation in a manner that provides meaningful information to consumers, particularly as it would likely only be present in minute amounts in the final food, if at all.

While it was acknowledged that P100 is a new treatment method, FSANZ was of the view that 'newness' is not in itself a reason to require labelling. Additionally, the proposed regulatory approach is consistent with the regulatory approach adopted by the USA, Canada and The Netherlands. These countries do not require P100 to be labelled.

FSANZ has reviewed the preferred approach and considered the views of submitters, noting that consumers did not express concerns on the use of P100 on solid RTE foods during either round of public consultation. Based on the rationale presented above, FSANZ is maintaining the usual approach for the labelling of processing aids, and will not require the specific ingredient labelling of P100.

3.2.5 Analytical methods for determining presence of P100 in food

The Applicant provided analytical methods for determining the presence of P100 in food which is provided in Section 4.5 in SD1.

The Implementation Sub-Committee's (ISC's)³ new Expert Advisory Group (EAG) set up to provide expert technical advice to FSANZ on analytical methods related to its standard development work was raised in submissions to this Application. The EAG considered this Application at its first meeting in March 2012 but concluded that, since the assessment was close to being finalised, it was not appropriate to provide any expert comments. The EAG further noted that there were analytical methods available in the Application and provided in FSANZ's reports. However, it did not check or offer comments on these methods.

It is pertinent to note that the role of the EAG is to provide expert technical advice on analytical matters early in the assessment process to allow FSANZ time to consider this advice within its statutory timelines.

3.2.6 Specification for P100 *Listeria* phage preparation

There were 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.

³ <http://www.health.gov.au/internet/main/publishing.nsf/Content/foodsecretariat-isc.htm>

Therefore, a specification for P100 has been approved for inclusion in the Schedule for Standard 1.3.4. Specifications for lead and arsenic are addressed by the existing requirements of clause 4 of Standard 1.3.4.

3.2.7 Summary of submissions

Consultation is a key part of FSANZ's standards development process. FSANZ acknowledges the time taken by individuals and organisations to make submissions on this Application.

Every submission on an application is reviewed by FSANZ staff, who examine the issues identified and prepare a response to those issues. The submissions are valued and all contribute to the rigour of our assessment.

Submissions on the draft variations to the Code were called for between 16 March and 27 April 2012. Eight submissions were received, of which five supported the approval of P100 for the proposed purpose and three did not provide a position. However, seven submissions, which were all from government agencies with responsibility for enforcing or assessing compliance with the Code, raised a number of issues for FSANZ's consideration. No submitters raised concerns about the safety of adding P100 to treat various solid RTE foods as proposed by the Applicant. In addressing the issues raised by submitters, FSANZ obtained further clarification and information from the Applicant and held further discussions with the jurisdictional submitters.

A number of common themes relating to the technical aspects of the Application were identified in the submissions including:

- persistence of bacteriophage on foods
- ongoing functionality
- mode of action
- development of resistance to bacteriophage by the bacteria
- methodology for bacteriophage treated foods.

The first three points considered together were used to argue that the P100 bacteriophage preparation should be considered a food additive rather than a processing aid. Many submitters referred to two recent scientific opinions from the European Food Safety Authority (EFSA) on the use and mode of action of bacteriophages (EFSA 2009) and the safety and efficacy of P100 on raw fish (EFSA 2012).

The submitters' issues and FSANZ's responses are summarised in Table 2, while detailed responses to the key issues raised are provided in SD2.

Table 2: Summary of issues raised in submissions

Issue	Raised by	FSANZ Response (including any amendments to drafting)
Assurance of efficacy and prevention of resistance development (reduced sensitivity)		
Efficacy data on each food category.	Dairy Food Safety Victoria and the Department of Health, Victoria	FSANZ assessed efficacy data for P100 or comparable phage for treating each of the food categories and concluded it was efficacious (see section 5.2 and annex 1 of SD1). FSANZ has only approved food categories that have been assessed and where P100 has been shown to be efficacious (section 3.1.2).
Resistance development and the need to monitor	Food Policy and Programs Branch, South Australia Health	FSANZ has emphasised the need to carry out continuous monitoring of food processing premises, and the Applicant has provided a commitment to continuously work with food manufacturers who use P100 to prevent resistance development (section 3.1.3).
Prevention of reintroduction of phage treated product to processing facilities is a key measure to minimise resistance development.	Ministry for Primary Industries (New Zealand) (called Ministry of Agriculture and Forestry when submission received)	Food manufacturers need to be made aware that it is inappropriate practice to reintroduce contaminated product that has been treated with phage for reprocessing into the plant under GMP and GHP (unless the product has been treated to inactivate the phages, usually by thermal treatment). The same situation exists for using ingredients treated with P100 brought into a plant. Such practices are required to limit resistance development (section 3.1.3).
Establishing tests to investigate potential resistance development/reduced susceptibility of bacteria to biocides and key therapeutic antimicrobials	Dairy Food Safety Victoria and the Department of Health, Victoria	FSANZ agrees with the EFSA 2012 opinion which concluded that, "based on the properties of P100 ..., it is concluded that the use of this bacteriophage for the removal of <i>L. monocytogenes</i> surface contamination of raw fish under the conditions specified by the applicant is unlikely to result in the potential emergence of reduced susceptibility to biocides and/or resistance to key therapeutic antimicrobials".
Nature of the technological function - processing aid or food additive?		
Non-ongoing nature of the technological function	NSW Food Authority	FSANZ's original assessment dealing with this issue is provided in section 5 and Annex 1 of SD1 and summarised in section 3.1.2. FSANZ performed some further detailed analysis to further address this issue in SD2.
P100 be classified as a food additive; suggest labelling in ingredients list	Food Technology Association of Australia	See section 3.2.1 as to why it is inappropriate to consider P100 as a food additive for treating solid RTE foods.

Issue	Raised by	FSANZ Response (including any amendments to drafting)
<p>Consider P100 as a live microbial preparation like yeasts or probiotics which are considered 'foods' and so already permitted as a processing aid. Should be categorised as either a novel food or food additive</p>	<p>Food Policy and Programs Branch, South Australia Health</p>	<p>FSANZ did not consider P100 as a food (ingredient or novel) for a number of reasons:</p> <ul style="list-style-type: none"> • The Applicant requested permissions as a processing aid and other international agencies consider it as a processing aid. • Food use of phages is new, so full assessment and consideration of regulatory opinions is appropriate. • To provide regulatory certainty; permission would be listed in the Standard, along with conditions of use if permitted. • Not all phages can be considered safe for use, therefore assessment of safety and efficacy for the proposed purpose was considered appropriate. <p>FSANZ does not agree with the suggestion of P100 considered as a food additive for the reasons explained in the report. FSANZ concludes it should not be considered a novel food because it performs a technological function (either as a food additive or processing aid) when it is added to food, being to eradicate or decrease <i>L. monocytogenes</i> on the surfaces of various solid RTE foods.</p>
<p>Would the phage behave as a food additive in products with purge/cook out/exudate liquids?</p>	<p>Queensland Health</p>	<p>P100 would be expected to function as a food additive when the treated food is covered or partially covered by liquid when the food is initially treated, for example mozzarella cheese covered in brine. However, this would not be the case where the food when initially treated was not immersed in liquid, such as sliced ham, that after being packaged and stored exuded liquid.</p>
<p>Categorisation as a food additive under Standard 1.3.1 (Schedule 5), as it 'retards or prevents the deterioration of the food by microorganisms'.</p>	<p>NSW Food Authority</p>	<p>The important point for classifying P100 is what technological function it is performing during the production or shelf life of the particular type of food it is applied to.</p>
<p>Labelling</p>		
<p>If labelled as a food additive, the application of phage would not need to be limited.</p>	<p>NSW Food Authority</p>	<p>The Application specifically sought approval of P100 as a processing aid for solid RTE foods. FSANZ has addressed the issue of why it considers P100 performs the technological function for the proposed purpose as a processing aid and not a food additive in detail in section 3.1.2.</p>
<p>Consumer expectations for labelling where a live organism is being added to food. Consumers may be misinformed due to lack of labelling</p>	<p>Food Policy and Programs Branch, South Australian Health Ministry for Primary Industries (New Zealand)</p>	<p>FSANZ's assessment on labelling P100 treated food is provided in section 3.2.4.</p>

Issue	Raised by	FSANZ Response (including any amendments to drafting)
Analytical methods		
<p>Input, as well as a timeline for consideration, by new EAG for analytical methods required. If <i>Listeria innocua</i> is used for production of the phage, <i>Listeria</i> spp may still be detected in the food when <i>L. monocytogenes</i> is not detected.</p>	<p>Queensland Health NSW Food Authority</p>	<p>The ISC EAG set up to consider analytical methods related to FSANZ's standards development work considered it was too late in the statutory timelines to realistically contribute (section 3.2.5). The EAG further noted that analytical methods are available as part of the Application and are contained in the report, but it did not make assessment of these methods.</p> <p>Detection of the production strain of <i>L. innocua</i> in treated food is considered unlikely due to the filtration steps during the downstream processing following incubation and quality assurance sampling of product for <i>Listeria</i> spp. (section 4.3 of SD1).</p>
<p>Potential for reactivation of bacteriophages exists when sampling and analysing for <i>L. monocytogenes</i> during sample homogenisation to produce artificially low levels</p>	<p>NSW Food Authority</p>	<p>The possibility of phages being released from the surface certainly exists. Occasionally such phages may even interact with cells released during the process. FSANZ has queried the Applicant who confirms that from experimental results it is shown that this does not significantly alter the results for low bacterial numbers. The main reason for the lack of this occurring is due to the short time taken during homogenizing the sample, as well as the dilution effect of the buffering agent. This is discussed and addressed in more detail in section 2.5 of SD2.</p>
Definitions and explanatory notes in permission		
<p>Editorial note in the permission relating to solid food should be clarified</p>	<p>Food Policy and Programs Branch, South Australian Health Queensland Health</p>	<p>After further internal consideration and discussions with jurisdictions it was agreed to simplify the permission as discussed in section 3.2.2 and remove the editorial note altogether.</p>
<p>Propose including the definition for RTE food in Standard 1.3.3 only since including it across the Code requires wider policy consideration.</p>	<p>Ministry for Primary Industries (New Zealand)</p>	<p>FSANZ agreed with this suggestion. The amended drafting does not include a definition for RTE food, but uses the same words incorporated into a new definition in Standard 1.3.3 of "approved food for use of phage" (section 3.2.2 and attachment A).</p>
<p>Include editorial note in Standard 3.2.2 indicating that RTE is included in Standard 1.1.1. One definition of RTE food is required in the Code.</p>	<p>Queensland Health NSW Food Authority</p>	<p>FSANZ notes these comments, however the amended drafting no longer refers to the definition of RTE food.</p>
<p>Alternative words for drafting provided, including a purpose clause in the permission.</p>	<p>Ministry for Primary Industries (New Zealand)</p>	<p>FSANZ appreciated the suggested amendments to the drafting. FSANZ considered these along with further discussions internally and with jurisdictions and amended the drafting.</p>

Issue	Raised by	FSANZ Response (including any amendments to drafting)
Drafting complicated by creating a category of foods that are solid and not wholly or partly covered in liquid. P100 may have an ongoing function in solid foods with more moisture.	Food Branch, Department of Agriculture, Fisheries and Forestry NSW Food Authority Queensland Health	FSANZ notes the concern for compliance of the permission as drafted dealing with solid food partially or wholly covered in liquid. Therefore the final drafting has been simplified (see section 3.2.2 and attachment A).
Use of the terms ‘anti-listerial’ or ‘antilisterial’ is unusual; suggests the term ‘listericidal’ as used by EFSA and Codex is a better term.	Ministry for Primary Industries (New Zealand)	FSANZ notes that Codex uses the term ‘listericidal’ and so agreed and therefore amended the word used in the drafting as well as in the report. However, FSANZ notes that the term ‘anti-listerial’ as well as ‘listericidal’ has also been used by EFSA in its recent phage opinions so the terms seem to be interchangeable.
The need for bacteriophage treatment and method of use		
The use of P100 undermines the application and outcomes of GMP to eliminate <i>L. monocytogenes</i> as the use of P100 may be seen as a “quick fix”.	Queensland Health	P100 is intended for use as an additional technology complementary to GMP and listericidal processes already in place.
Inadequate data to enable firm conclusions on persistence or activity of P100 in stored fish. These aspects as well as changes in <i>L. monocytogenes</i> counts should be evaluated during storage	Dairy Food Safety Victoria and the Department of Health, Victoria	This issue was raised by EFSA in its 2012 opinion on the use of P100 to treat raw fish, which is different to the current Application which is to use P100 to treat solid RTE foods. Considering the data presented, FSANZ is of the view that there is sufficient evidence to show the efficacy of P100 on the range of solid RTE foods for which permission was sought by the Applicant. Consistent with the principles of GHP, users of P100 are expected to validate and optimise conditions for use for each product/process combination and each processing facility as discussed in section 3.2.3.
Release of bacteriophages from food surface due to syneresis or condensate	Dairy Food Safety Victoria and the Department of Health, Victoria	The data analysed in SD1 of trials that treated various solid RTE foods showed evidence of efficacy (section 5.2 and Annex 1 of SD1). It is not known if phages may be released from food surfaces and so not be as efficacious but what is known from the analysis of the data is they have a definite initial positive effect to reduce the levels of <i>L. monocytogenes</i> on the food surface.
Queries the adequacy of evidence of the activity of P100 in fruits, and if it is suitable only in short shelf-life foods	Ministry for Primary Industries (New Zealand)	The analysis of the scientific literature suggests the technological function of the applied phage particles is limited to a short period of time after treatment. Food manufacturers need to apply very high concentrations of phage particles to ensure good early control. As noted in section 3.2.3 food manufacturers should perform their own efficacy studies of using P100 to treat their food products under their conditions.

Issue	Raised by	FSANZ Response (including any amendments to drafting)
<p>As a surface treatment, P100 would not reach internal parts of the product and would not overcome post- treatment contamination.</p>	<p>Queensland Health</p>	<p>P100 is a surface treatment that will not address post treatment contamination. The method of application should be validated and optimised for use for different food types and manufacturing plants (section 3.2.3).</p>
Communication		
<p>Provide information on issues relating to analytical methods and usage suitable for relevant enforcement and compliance personnel.</p>	<p>Queensland Health</p>	<p>FSANZ notes this suggestion and believes this is a role that is better undertaken by ISC whose role for considering guidance and consistent approaches to enforcement action by jurisdictions. FSANZ may raise this issue at an upcoming ISC meeting.</p>
Other		
<p>The need for the Applicant to contact the biosecurity authority -of Australia and Environmental Protection Authority of New Zealand</p>	<p>Ministry for Primary Industries (New Zealand)</p>	<p>The Applicant has been notified of the relevant regulatory agencies in both Australia and New Zealand to contact before importing the P100 preparation.</p>

3.3 Risk communication

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

Communication included website fact sheets, media releases at the start of both consultation periods and news items in *Food Standards News*.

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. Special consultations with jurisdictional submitters were held after both calls for submissions.

The Applicant, individuals, and organisations making submissions on this Application were notified at each stage of the Application. The Board's decision has been 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.

4. Reasons for decision

The variation to the Code to permit the sale and use of the bacteriophage preparation P100 for the control of *L. monocytogenes* in specific solid RTE foods in Australia and New Zealand was approved based on the best available scientific evidence, for the following reasons:

- The safety assessment did not identify any public health and safety concerns associated with using P100 to treat food.
- P100 is effective at reducing levels of *L. monocytogenes* on the surface of solid RTE foods evaluated.
- There is no appreciable ongoing technological function of P100 when it is applied to the surface of various solid RTE foods, and therefore fits into the category of processing aids. This is consistent with international approaches.
- There were no measures that would be more cost-effective than a variation to Standard 1.3.3 that could achieve the same result.

FSANZ had regard to the following matters under section 29 of the FSANZ Act:

- *whether costs that would arise from a food regulatory measure developed or varied as a result of the Application outweighed the direct and indirect benefits to the community, Government or industry that would arise from the development or variation of the food regulatory measure*

The Office of Best Practice Regulation (OBPR) provides a standing exemption (RIS ID: 12065) from the need to assess if a Regulation Impact Statement is required for applications and proposals relating to processing aids as they are minor or machinery in nature and their use would be voluntary. However, FSANZ performed a limited impact analysis and the conclusions are provided below.

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 concluded 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.

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.

Approval of 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. Testing laboratories may require up skilling of staff as well as investment in analytical techniques.

- *whether other measures (whether available to FSANZ or not) would be more cost-effective than a food regulatory measure developed or varied as a result of the Application*

There are no other measures that would be more cost effective to achieve the same outcomes than variations to the Code.

- *any relevant New Zealand standards*

There are no relevant New Zealand only standards, since Standards 1.3.3 and 1.3.4 apply to New Zealand.

- *any other relevant matters.*

No other relevant matters were identified.

4.1 Addressing FSANZ's objectives for standards-setting

FSANZ has considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment of this Application as follows.

4.1.1 Protection of public health and safety

No public health and safety issues were identified in the safety assessment (see section 3.1.3). On the basis of the evidence provided, P100 is considered safe for the proposed use.

4.1.2 The provision of adequate information relating to food to enable 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 packaged 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.

4.1.3 The prevention of misleading or deceptive conduct

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

4.1.4 Subsection 18(2) considerations

FSANZ has also had regard to the matters set out in subsection 18(2):

- *the need for standards to be based on risk analysis using the best available scientific evidence*

The Applicant submitted a dossier including published articles in peer reviewed journals, which described experimental details and data of products treated with P100. In addition, FSANZ gathered other scientific publications including classification data and further analysed data submitted by the Applicant for investigating the nature of the technological function.

- *the promotion of consistency between domestic and international food standards*

In assessing this Application, FSANZ considered the approaches taken by the US FDA, USDA, Health Canada and EFSA on the use of bacteriophages and P100 in various food products for controlling *L. monocytogenes*.

- *the desirability of an efficient and internationally competitive food industry*

The permission for the use of P100 to treat the surface of various solid RTE foods improves the confidence of the Australian and New Zealand food industry in their *L. monocytogenes* control programs. Permitting Australian and New Zealand food industries to use P100 ensures they also have the accessibility to the same technology as their international counterparts to control *L. monocytogenes*.

- *the promotion of fair trading in food*

This matter is not applicable for this Application.

- *any written policy guidelines formulated by the Ministerial Council.*

The 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 granted 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'),
- the addition of the substance to food is safe for human consumption,
- 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.

FSANZ has determined that permitting the use of P100 as a processing aid to treat the surfaces of various solid RTE foods to assist in the control of *L. monocytogenes* is consistent with the above policy principles.

5. References

Codex (2007) Guidelines on the application of general principles of food hygiene to the control of *Listeria monocytogenes* in foods CAC/GL 61

http://www.codexalimentarius.org/download/standards/10740/CXG_061e.pdf

Accessed 31 May 2012

EFSA (2009) The use and mode of action of bacteriophages in food production. The EFSA Journal (2009) 1076:1-26

EFSA (2012) Scientific opinion on the evaluation of the safety and efficacy of Listex™ P100 for the removal of *Listeria monocytogenes* surface contamination of raw fish. EFSA Journal (2012) 10(3):2165

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

<http://www.foodstandards.gov.au/consumerinformation/listeria/listeriarecallguidel1321.cfm>

Accessed 31 May 2012

FSANZ (2011) Food recall statistics. Canberra, Australia.

<http://www.foodstandards.gov.au/consumerinformation/foodrecalls/foodrecallstats.cfm>

Accessed 31 May 2012

Attachments

- A. Approved variations to the *Australia New Zealand Food Standards Code*
- B. Explanatory Statement
- C. Draft Food Regulatory Measure

Attachment A – Approved 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 1.3.3** is varied by

[1.1] inserting in alphabetical order in clause 1

“**approved food for use of phage** means food that –

- (a) is ordinarily consumed in the same state as that in which it is sold; and
- (b) is solid; and
- (c) is one of the following –

- (i) meat;
- (ii) meat product;
- (iii) fish;
- (iv) fish product;
- (v) fruit;
- (vi) fruit product;
- (vii) vegetable;
- (viii) vegetable product;
- (ix) cheese; and

(d) is not one of the following –

- (i) nuts in the shell and whole;
- (ii) raw fruits and vegetables that are intended for hulling, peeling or washing by the consumer.”

[1.2] inserting in alphabetical order in the Table to clause 14 –

“ <i>Listeria</i> phage P100	Listericidal treatment for use on approved food for use of phage	GMP”
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[1.3] inserting after the Table to clause 14

“Editorial note

If *Listeria* phage P100 has an ongoing technological function it ceases to be a processing aid as defined in subclause 1(1), and operates instead as a food additive. For example, *Listeria* phage P100 may have an ongoing technological function when introduced to liquids. Standard 1.3.1 does not permit the use of *Listeria* phage P100 as a food additive.”

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

“Specification for *Listeria* phage P100

Biological classification

Order	<i>Caudovirales</i>
Family	<i>Myoviridae</i>
Subfamily	<i>Spounaviridae</i>
Genus	Twort-like
Species	<i>Listeria</i> phage P100
GenBank Accession Number	DQ004855"

Attachment B – 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 (RTE) foods. The Authority considered the Application in accordance with Division 1 of Part 3 and has approved draft variations to Standards 1.3.3 and 1.3.4.

Following consideration by COAG Legislative and Governance Forum on Food Regulation⁴, section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

Section 94 of the FSANZ Act specifies that a standard, or a variation of a standard, in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sunseting under the *Legislative Instruments Act 2003*.

2. Purpose and operation

The Authority has approved permission for the use of P100 as a processing aid to treat the surface of specific solid RTE foods to reduce the concentration of the food pathogen *L. monocytogenes* under the conditions of GMP. The specific RTE foods types that P100 may treat are meat and meat products, fish and fish products, fruit and fruit products, vegetable and vegetable products and cheese.

There are no specifications for P100 in the primary or secondary references in Standard 1.3.4 so a specification for P100 has been inserted into this Standard. Permissions for new processing aids need to be linked to appropriate specifications for the product to ensure only appropriate material is used to treat food.

3. Documents incorporated by reference

The variations to food regulatory measures do 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 of A1045 included two rounds of public comment following an assessment and the preparation of draft variations and associated reports.

A summary of the assessment was released in September 2011 for public comment.

⁴ Previously known as the Australia and New Zealand Food Regulation Ministerial Council

The draft variations were subsequently released for consultation on 16 March 2012 for a six-week consultation period.

A Regulation Impact Statement was not required because the proposed variations to Standards 1.3.3 and 1.3.4 are likely to have a minor impact on business and individuals.

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 an entry for *Listeria* phage P100 into the Table to clause 14 of Standard 1.3.3 to permit the use of P100 as a processing aid to surface 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). P100 can be used at Good Manufacturing Practice (GMP) as there is no maximum usage level proposed, and the level of use is as appropriate following GMP.

The permission does not apply to whole nuts in the shell and raw fruits and vegetables that are intended for hulling, peeling or washing by the consumer, which is part of the existing definition of ready-to-eat foods in Standard 3.2.2.

As *Listeria* phage P100 may have an ongoing technological function when introduced to liquids, an editorial note has been added after the Table to clause 14 to highlight this property. An ongoing technological function is a characteristic of food additives and not processing aids. *Listeria* phage P100 is not permitted for use as a food additive under Standard 1.3.1.

Item [2] inserts a specification for *Listeria* phage P100 into the Schedule to Standard 1.3.4.

Attachment C – Draft variations to the *Australia New Zealand Food Standards Code*

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