Environmental Protection Authority
Te Mana Rauhī Taiao

APPLICATION FORM
Release with Controls

To obtain approval to release new organisms with controls

(Through importing for release or releasing from containment)

Send to Environmental Protection Authority preferably by email (neworganisms@epa.govt.nz) or alternatively by post (Private Bag 63002, Wellington 6140)

Application Number

APP202089

Date

Completing this application form

1. This form has been approved under section 38A of the Hazardous Substances and New Organisms (HSNO) Act 1996. It only covers conditional release/release with controls of any new organism (including genetically modified organisms (GMOs)) that is to be imported for release or released from containment. If you wish to make an application for another type of approval or for another use (such as an emergency, special emergency, release without control or containment), a different form will have to be used. All forms are available on our website.
2. It is recommended that you contact an Advisor at the Environmental Protection Authority (EPA) as early in the application process as possible. An Advisor can assist you with any questions you have during the preparation of your application including providing advice on any consultation requirements.
3. Unless otherwise indicated, all sections of this form must be completed for the application to be formally received and assessed. If a section is not relevant to your application, please provide a comprehensive explanation why this does not apply. If you choose not to provide the specific information, you will need to apply for a waiver under section 59(3)(a)(ii) of the HSNO Act. This can be done by completing the section on the last page of this form.
4. Any extra material that does not fit in the application form must be clearly labelled, cross-referenced, and included with the application form when it is submitted.
5. Please add extra rows/tables where needed.
6. You must sign the final form (the EPA will accept electronically signed forms) and pay the application fee (including GST) unless you are already an approved EPA customer. To be recognised by the EPA as an “approved customer”, you must have submitted more than one application per month over the preceding six months, and have no history of delay in making payments, at the time of presenting an application.
7. Information about application fees is available on the EPA website.
8. All application communications from the EPA will be provided electronically, unless you specifically request otherwise.

Commercially sensitive information

9. Commercially sensitive information must be included in an appendix to this form and be identified as confidential. If you consider any information to be commercially sensitive, please show this in the relevant section of this form and cross reference to where that information is located in the confidential appendix.
10. Any information you supply to the EPA prior to formal lodgement of your application will not be publicly released. Following formal lodgement of your application any information in the body of this application form and any non-confidential appendices will become publicly available.
11. Once you have formally lodged your application with the EPA, any information you have supplied to the EPA about your application is subject to the Official Information Act 1982 (OIA). If a request is made for the release of information that you consider to be confidential, your view will be

considered in a manner consistent with the OIA and with section 57 of the HSNO Act. You may be required to provide further justification for your claim of confidentiality.

Definitions

Containment	Restricting an organism or substance to a secure location or facility to prevent escape. In respect to genetically modified organisms, this includes field testing and large scale fermentation
Controls	Any obligation or restrictions imposed on any new organism, or any person in relation to any new organism, by the HSNO Act or any other Act or any regulations, rules, codes, or other documents made in accordance with the provisions of the HSNO Act or any other Act for the purposes of controlling the adverse effects of that organism on people or the environment
Genetically Modified Organism (GMO)	Any organism in which any of the genes or other genetic material: • Have been modified by *in vitro* techniques, or • Are inherited or otherwise derived, through any number of replications, from any genes or other genetic material which has been modified by *in vitro* techniques
New Organism	A new organism is an organism that is any of the following: • An organism belonging to a species that was not present in New Zealand immediately before 29 July 1998; • An organism belonging to a species, subspecies, infrasubspecies, variety, strain, or cultivar prescribed as a risk species, where that organism was not present in New Zealand at the time of promulgation of the relevant regulation; • An organism for which a containment approval has been given under the HSNO Act; • An organism for which a conditional release approval has been given under the HSNO Act; • A qualifying organism approved for release with controls under the HSNO Act; • A genetically modified organism; • An organism belonging to a species, subspecies, infrasubspecies, variety, strain, or cultivar that has been eradicated from New Zealand; • An organism present in New Zealand before 29 July 1998 in contravention of the Animals Act 1967 or the Plants Act 1970. This does not apply to the organism known as rabbit haemorrhagic disease virus, or rabbit calicivirus A new organism does not cease to be a new organism because: • It is subject to a conditional release approval; or • It is a qualifying organism approved for release with controls; or • It is an incidentally imported new organism
Release	To allow the organism to move within New Zealand free of any restrictions other than those imposed in accordance with the Biosecurity Act 1993 or the Conservation Act 1987
Unwanted Organism	As defined in section 2 of the Biosecurity Act 1993 http://www.legislation.govt.nz/act/public/1993/0095/latest/DLM314623.html?src=qs

1. Applicant details

1.1. Applicant

Company Name: Micreos

Contact Name: Dirk de Meester

Job Title: Buisness Development Director

Physical Address: Nieuwe Kanaal 7P, 6709 PA Wageningen

Postal Address (provide only if not the same as the physical)**:**

Phone (office and/or mobile): +31 6 46048503

Fax: +31 317 410055

Email: d.demeester@micreos.com

1.2. New Zealand agent or consultant (if applicable)

Company Name:

Contact Name:

Job Title:

Physical Address:

Postal Address (provide only if not the same as the physical)**:**

Phone (office and/or mobile):

Fax:

Email:

2. Information about the application

2.1. Brief application description

Approximately 30 words about what you are applying to do

To import and release *Listeria* phage P100 in the product LISTEX™, for use as a processing aid to eradicate or decrease *Listeria monocytogenes* in food products.

2.2. Summary of application

Provide a plain English, non-technical description of what you are applying to do and why you want to do it

We (Micreos) develop and market organic antimicrobials aimed at food borne pathogens, for use in food preparation. LISTEX™ targets *Listeria monocytogenes*, and is used in food processing facilities either by immersion or spraying. The use of LISTEX results in a siginificant reduction of contaminated food products entering into the market place.

LISTEX™ is currently used in: USA, Canada, EU (UK, Ireland, The Netherlands, Germany, Italy, Spain, Switzerland, France, Austria). Our product is also being marketed in Brasil, Chile, Argentina, Venezuela, Mexico, Japan, Israel, South Africa, Vietnam, Korea, Iceland, Norway, Sweden, Finland, Estonia, Lithuania.

We would like to introduce this product to the New Zealand market, where it could be used in a range of food preparation facilities for example RTE protein products such as deli meats, cheese, salads and fish.

We received approval by FSANZ approval to include bacteriophage (Listeria phage) preparation Listex™ P100 (subsequently called P100) 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) food products for human consumption”.

2.3. Background and aims of application

This section is intended to put the new organism(s) in perspective of the wider activitie(s) that they will be used in. You may use more technical language but all technical words must be included in a glossary

Bacteriophages are the most abundant biological entities on earth and are present wherever bacteria exist.

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. They infect specific strains of bacteria.

Phage P100 infects all species within the genus Listeria excepting L. grayi strains. The susceptible species are: *L. monocytogenes, L. ivanovii, L. innocua, L. welshimeri* and *L. seeligeri*.

P100 bacteriophage is not able to infect any other bacteria except Listeria species (including *L. monocytogenes*), and they are unable to infect plant, animal or human cells.

Ready-to-eat (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.

Listeria monocytogenes is a problem in the food industry because the pathogen enjoys the food processing conditions and is particularly dangeroussince it continues to grow at refrigeration temperatures so during the shelf life of many convenience products.

Analysis performed by FSANZ confirms that the use of P100, 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.

3. Information about the new organism(s)

3.1. Name of organism

Identify the organism as fully as possible

Non-GMOs - Provide a taxonomic description of the new organism(s).

GMOs – Provide a taxonomic description of the host organism(s) and describe the genetic modification.

Both -

- Describe the biology and main features of the organism including if it has inseparable organisms.
- Describe if the organism has affinities (e.g. close taxonomic relationships) with other organisms in New Zealand.
- Could the organism form an undesirable self-sustaining population? If not, why not?
- How easily could the new organism be recovered or eradicated if it established an undesirable self-sustaining population?

The organism is *Listeria* phage P100.

P100 belongs to the order Caudovirales, the family Myoviridae (phages with contractile tails), the subfamily Spounavirinae and the genus Twortlikevirus. P100 is a bacteriophage, and is the active component in the product LISTEX P100, which is used as a preventative measure against *Listeria monocytogenes* contamination in food preparation.

Phage P100 was isolated from waste water at a dairy plant in southern Germany (Carlton et Al. 2005).

Phage P100 infects all species within the genus *Listeria* excepting *L. grayi* strains. The susceptible species are: *L. monocytogenes*, *L. ivanovii*, *L. innocua*, *L. welshimeri* and *L. seeligeri*. These host species have a global distribution and are found ubiquitously in the environment. *Listeria* are primarily saprophytic soil organisms.

P100 and the production organism are completely characterized as concluded in FSANZ Approval report for Application A1045.

Almost identical P100 phages have been isolated in other European countries, the US and New Zealand (see Appendix 1).

A phage isolated in New Zealand was investigated for its potential to control the growth of *Listeria* on ready-to-eat poultry products. The authors noted that the phage was likely to belong to the SPO1-like *Listeria* phages to which P100 belongs (Bigot et al. 2011). There is no definitive species concept in the Caudovirales and therefore we contend that P100 is an isolate of a global species and this is consistent with the theory of the viriosphere (Hambly and Suttle 2005).

Bacteriophage populations are self-limiting. They rely on their host for propagation. Without host bacteria present bacteriophage populations will decline and disappear. They are rapidly degraded in the environment through a number of mechanisms: i.e. UV-light, organic acids, salts, proteolytic enzymes and through adsorption to particles. This is perhaps best illustrated by the fact that to date over 350 different phages infecting members of the genus Listeria have been isolated without any of these phages becoming the dominant species other than in a micro-environment.

Phage populations are by definition self-limiting and will not establish itself as an undesirable self-sustaining population.

3.2. Regulatory status of the organism

Is the organism that is the subject of this application also the subject of:

An innovative medicine application as defined in section 23A of the Medicines Act 1981?

☐ Yes ☒ No

An innovative agricultural compound application as defined in Part 6 of the Agricultural Compounds and Veterinary Medicines Act 1997?

☐ Yes ☒ No

4. Māori engagement

Discuss any engagement or consultation with Māori undertaken and summarise the outcomes. Please refer to the EPA policy 'Engaging with Māori for applications to the EPA' on our website (www.epa.govt.nz) or contact the EPA for advice.

5. Risks, costs and benefits

Provide information of the risks, costs and benefits of the new organism(s).

These are the positive and adverse effects referred to in the HSNO Act. It is easier to regard risks and costs as being adverse (or negative) and benefits as being positive. In considering risks, cost and benefits, it is important to look at both the likelihood of occurrence (probability) and the potential magnitude of the consequences, and to look at distribution effects (who bears the costs, benefits and risks).

Consider the adverse or positive effects in the context of this application on the environment (e.g. could the organism cause any significant displacement of any native species within its natural habitat, cause any significant deterioration of natural habitats or cause significant adverse effect to New Zealand's inherent genetic diversity, or is the organism likely to cause disease, be parasitic, or become a vector for animal or plant disease?), human health and safety, the relationship of Māori to the environment, the principles of the Treaty of Waitangi, society and the community, the market economy and New Zealand's international obligations.

You must fully complete this section referencing supporting material. You will need to provide a description of where the information in the application has been sourced from, e.g. from in-house research, independent research, technical literature, community or other consultation, and provide that information with this application.

We are not aware of any risks to the environment that would result from the release of P100. This is because P100 can only infect Listeria spp. Also, in evaluating LISTEX™, FSANZ concludes that the preparation does not present any food safety issues based on 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. Bioinformatic analyses revealed that none of the putative phage proteins has any homologies to genes or proteins of Listeria or any other bacteria which are known or suspected to be toxins, pathogenicity factors, antibiotic resistance determinants, or any known allergens. (Carlton et Al 2005)

As a result of the presence of *L. monocytogenes* in food a number of food-poisoning outbreaks have been reported in a great number of cases with even fatal results. For that reason an effective control of *Listeria* at all stages of the food production process thus is relevant. Apart from GMP, HACCP and other measures aiming at prevention of *Listeria* or minimising conditions of outgrowth of it, the application of the bacteriophage P100 is an additional measure to control *Listeria* in food.

L. monocytogenes has been associated with a number of food-poisoning outbreaks related to foods such as soft cheeses, processed meat, poultry, and vegetables. The symptoms can range from severe diarrhea to death. It was estimated that approximately 2,000 hospitalizations and 500 deaths occur annually in the United States alone, as a result of the consumption of foods contaminated with *Listeria monocytogenes* (Mead, 1999). Thus mortality rate is estimated at 25%

Infection usually occurs via ingestion of contaminated dairy products, raw vegetables, or meats and is favored by the ability of *L. monocytogenes*, a facultative anaerobic bacterium, to survive and grow at refrigerator temperatures.

Usually foods will be contaminated during fermentation, processing, storage, or even packaging of foods whereas infection also may occur by direct contact and during slaughter of infected animals.

Listeria has been isolated from a broad variety of foods that include milk, cheese and other dairy products, meat and meat products, poultry, fish and seafood, vegetables and fruits (Farber, 1991; Ryser 1991).

Many countries have adopted a zero tolerance policy for the organism in food, which has led to the recall of many products from supermarket shelves with economic losses. The persistence of *L.monocytogenes* in food products proves that it is difficult to eradicate this pathogen using currently available methods. In addition to all presently available precautionary measures, the application of bacteriophages will be an attractive approach.

Bacteriophages can be regarded as natural enemies of bacteria, and therefore are logical candidates to control food borne bacterial pathogens like *Listeria*.

The attributes of bacteriophages include the following:

- they are designed to kill live bacterial target cells,
- they generally do not cross species or genus boundaries, and will therefore not affect desired bacteria in foods (e.g., starter cultures), and commensals in the gastrointestinal tract, or accompanying bacterial flora in the environment; moreover,
- phages are generally composed entirely of proteins and nucleic acids, so their breakdown products consist exclusively of amino acids and nucleic acids.

Bacteriophages thus are not xenobiotics, and, unlike antibiotics and antiseptic agents, their introduction into, and distribution within a given environment may be seen as a natural process.

With respect to their potential application for the biocontrol of undesired pathogens in foods, feeds, and related environments, it should be considered that phages are the most abundant self-replicating units in our environment, and are present in significant numbers in water and foods of various origins, in particular fermented foods (reviewed by Sulakvelidze and Barrow, 2005). On fresh and processed meat and meat products, more than 10^8 viable phage per gram are often present (Kennedy and Bitton, 1987). It is a fact that phages are routinely consumed with our food in quite significant numbers. Moreover, phages are also normal commensals of humans and animals, and are especially abundant in the gastrointestinal tract (Furuse, 1987; Breitbart, 2003).

FSANZ has tested the product and found the use of LISTEX to eradicate or decrease *Listeria monocytogenes* on specific solid RTE foods to be "technologically justified and demonstrated to be effective in achieving its stated purpose' (referencing the FSANZ approval, and papers that demonstrated the efficacy, eg Guenther, 2009).

Approval of this application will enable LISTEX to be used by RTE food manufacturers in New Zealand, this is a valuable tool for NZ food industry, and many manufacturers are keen to make use of this valuable tool.

In New Zealand around 25 cases occur annually. Of those about 20% are associated with pregnancy or newborn babies. Between 5 and 7% of people affected by the disease die a year on average. The number of cases recorded here is similar to that found in countries with similar health status.

6. Proposed controls

Describe the controls you propose to mitigate potential risks (identified above).

We propose that P100 be released subject to a controls requiring that it only be imported and released in the form of the product called LISTEX, and can only be used for the FSANZ approved purpose in the manner described in the approval report A1045 by FSANZ issued 2 August 2012 . Specifically under the conditions of GMP.

Further we suggest inactivation of unused product as a control. This is easily achieved by:

- Temperature: rapidly inactivated at temperatures above 50°C.
- pH: inactivated at pH values less than 3. Inactivation proceeds faster at higher temperatures.
- Hypochlorine (HoCl. Rapid inactivation at low levels however >20 ppm is advised.

7. HSNO (Genetically Modified Organisms – Information Requirements for Segregation and Tracing) Regulations 2008

This section is for GMOs only

- What specific measures, if any, do you intend to take to keep the genetically modified organism(s) separate from other organisms, whether or not the other organisms are genetically modified or not?
- What specific measures, if any, do you intend to take to enable the genetically modified organism(s) to be traced after it is released with controls?
- What level of effectiveness do you expect these measures to achieve?
- If you do not intend to take any segregation or tracing measures please set out your reasons for not taking the measures.

Bacteriophage P100 is not a GMO.

8. Pathway determination and rapid assessment

This section is for Non-GMOs only

Under section 38BA of the HSNO Act your application may be eligible for a rapid assessment. The pathway for your application will be determined after its formal receipt, based on the data provided in this application form. If you would like your application to be considered for rapid assessment (as per the criteria below), we require you to complete the below section.

8.1. Discuss if your organism is an unwanted organism as defined in the Biosecurity Act 1993

P100 is not an unwanted organism as defined by the Biosecurity Act.

8.2. Discuss if it is highly improbable, after taking into account the proposed controls, that the organism after release:

- Could form self-sustaining populations anywhere in New Zealand (taking into account the ease of eradication)
- Could displace or reduce a valued species

- Could cause deterioration of natural habitats,
- Will be disease-causing or be a parasite, or be a vector or reservoir for human, animal, or plant disease
- Will have adverse effects on human health and safety or the environment

LISTEX™ P100 aims to control *Listeria monocytogenes* in modern food processing. Either by targeted spraying or immersion whilst the production is in operation. The processing facilities are obliged to operate under Good Manufacturing Practices (GMP) and along the guidance suggested by the Ministry of Primary Industries to control *Listeria monocytogenes* in ready-to-eat foods. Sanitation is part of these measures designed to kill possible contaminants such as Listeria monocytogenes and remove organic material. HACCP plans contain validated and audited processes to assure this. Since P100 will only be used in food processing facilities, the required controls are already incorporated in New Zealand law. Since LISTEX™ is comprised of a protein shell which will be denatured by all sanitizers for example at chlorine levels above 6 ppm or when hot water is used a temperatures above 45 celcius, the phages will be inactivated during each sanitation cycle. The phages on the product will be absorbed to the protein of the treated product and consumed.

Processing aids are not allowed to have a technical function in the final product. LISTEX™ is inactivated within 24 hours after addition to the food. This inactivation is caused by various factors such as adsorption of phages to particles, proteolytic degradation of the phage particle by chemicals and enzymes, temperature, salts and light (Suttle and Chen 1992; Garza and Suttle 1998; Hurst *et al*., 1980). Eventually, phages will fall apart into amino acids and nucleotides.

Rapid phage inactivation is caused largely by adsorption of the pages to the food matrix. It is commonly known that proteins adsorb to surfaces (Ruggiero *et al.*, 2005) and since phages consist of a protein hull containing DNA also phages are likely to adsorb. There are several interactions between the phage and the food surface that contribute to the strong binding:

- Hydrophobic interactions: the side chain of several amino acids is non-polar and hence interacts poorly with polar molecules like water. When non-polar residues are exposed at the surface of two different molecules, it is energetically more favourable for their non-polar surfaces to approach each other closely, displacing the water from between them.
- Ionic interaction: proteins contain both positively and negatively charged amino acids. These interact with and bind to other, oppositely charged groups.
- Hydrogen bonds: a strongly electronegative atom (e.g., oxygen, nitrogen) approaches a hydrogen atom which is covalently attached to a second strongly electronegative atom. These can be formed in the case of phages and foodstuffs between the –C=O group and the H-N- groups, and between –C=O groups and H-O- groups proteins and sugars.

Individually these bonds are much weaker than covalent bonds (typically about 20 times), but many of them together can have formidable strength. The first bond to occur brings the phage closer and holds it to the food surface, increasing the likelihood of additional bonds to form. This is the reason why adsorption only becomes stronger over time. Any one bond can be broken with relative ease, but for phages to desorb, all bonds must be broken simultaneously which is impossible.

Therefore, based on the biology of phages, and the controls we are proposing we consider that P100 will not be able to form a self-sustaining population, and it is highly improbable to impossible that any adverse effects could occur.

9. Other information

Add here any further information you wish to include in this application including if there are any ethical considerations that you are aware of in relation to your application.

Each possible ethical consideration perceivable speaks in favour of this natural antimicrobial. It targets a dangerous foodborne pathogen, saves human life, does not have any ecological footprint, is organic and will lead to a more sustainable society.

10. Checklist

This checklist is to be completed by the applicant

Application		**Comments/justifications**
All sections of the application form completed or you have requested an information waiver under section 59 of the HSNO Act	☒ Yes ☐ No (If No, please discuss with an Advisor to enable your application to be further processed)	NA
Confidential data as part of a separate, identified appendix	☐ Yes ☒ No	NA
Supplementary optional information attached:		
• Copies of additional references	☐ Yes ☐ No	
• Relevant correspondence	☐ Yes ☐ No	
Administration		
Are you an approved EPA customer?	☐ Yes ☒ No If Yes are you an: Applicant: ☐ Agent: ☐	
If you are not an approved customer, payment of fee will be by: • Direct credit made to the EPA bank account (preferred method of payment) Date of direct credit: • Cheque for application fee enclosed	☐ Yes ☐ No ☐ Payment to follow ☐ Yes ☐ No ☐ Payment to follow	
Electronic, signed copy of application e-mailed to the EPA	☐ Yes	

Signature of applicant or person authorised to sign on behalf of applicant

☒ I am making this application, or am authorised to sign on behalf of the applicant or applicant organisation.

☒ I have completed this application to the best of my ability and, as far as I am aware, the information I have provided in this application form is correct.

Signature	**Date**

Request for information waiver under section 59 of the HSNO Act

☐ I request for the Authority to waive any legislative information requirements (i.e. concerning the information that has been supplied in my application) that my application does not meet (tick if applicable).

Please list below which section(s) of this form are relevant to the information waiver request:

Appendices and referenced material (if any) and glossary (if required)

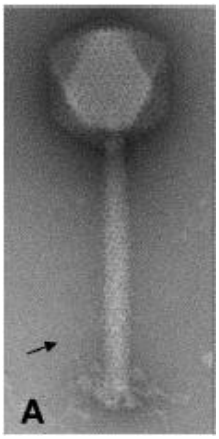
Appendix 1.

Bacteriophages are the most abundant self-replicating entities on earth. Estimates for their total numbers range from 10^{30} - 10^{31}. They prey on target bacteria and hence there is significant diversity in different phages.

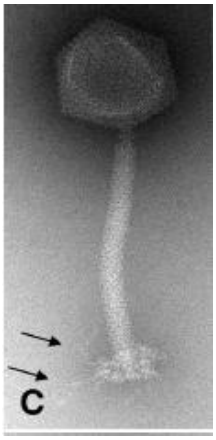
In a natural environment phages and bacteria keep each other in balance. As bacterial numbers rise phage can propagate on the elevated host levels. As a consequence bacterial numbers decline leaving progeny phage without hosts to further increase their numbers. Phage rapidly become inactivated by physical and chemical factors such as UV-light, denaturing and proteolytic compounds or simple adsorption to particles rendering them inactive. These events cycle in a Lotka-Volterra like relationship.

While many different types of phages for the different bacteria can be found the number of different phage types that infect a single species are limited. Analysis of 11 isolates of a phage species (φKMV) from different geographical locations (φKMV) revealed only very minor genetic differences with core genome regions being almost completely identical (Ceyssens et al. 2011).

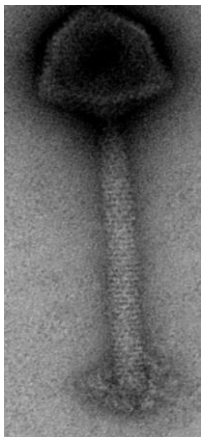
The presence of identical sequences is very different environments has also been investigated leading to the term viriosphere. The authors also point out that for certain bacteriophages the distribution is global (Hambly and Suttle 2005). Comparing phage populations in the Pacific ocean, Arctic ocean and Atlantic ocean also revealed identical species to be present (Angly et al. 2006). The authors showed that while the diversity of the phage population were large and identical species were found, abundance of the single phage species varied depending on local ecology. This means that the abundance of any one phage species is determined not by its presence in an ecosystem but by the ecosystem itself.



Phage A511



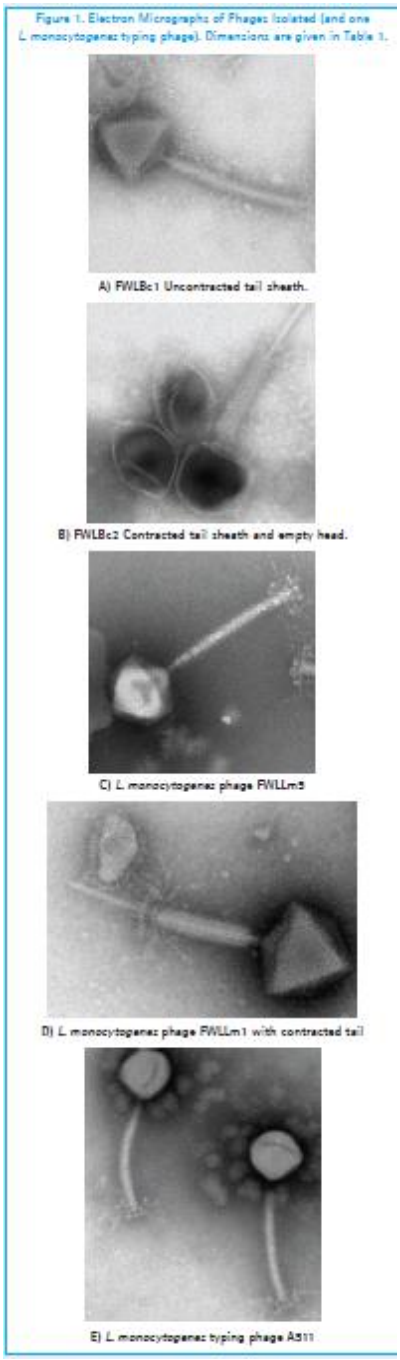
Phage P100



Phage P200

(no sequence data)

Evidence for global distribution of certain phage species such as T4 like E. coli phages and K-like Staphylococcal phages can be found in the literature as well as numerous other phage species such as phages lambda, T7 and Mu but the question that needs answering is this true for P100 as contained in Listex.



Micreos has 18 different isolates of this species. Two of these (A511 and P100) have been sequenced Dorscht et al. 2009). They are 97% identical. This can also be observed in restriction enzyme digests of genomic DNA which are highly similar with small variations. The other 16 isolates all have similar degrees of differences based on such an analysis. They all have extremely similar host ranges (plaque formation on >95% of all strains) although these host ranges are not completely identical. Electron microscopy reveals identical morphology of all these phages (genetic differences don't occur within the structural genes).

There is evidence that this phage species is also found in North America. A publication on q-PCR of a Listeria phage isolated in the US (Lis36) generates a the same PCR-product when P100 or A511 DNA is used as a template (For PCR primer sequence info see: Anderson et al . 2011).

While no sequence data is available phages with identical morphology have been isolated in New Zealand. They are almost certainly members of the SPO1-like Listeria phages.

These Listeria phages (right) were isolated by the Environmental Science and Research (ESR) staff at the Christchurch Science Center (CSC). The complete poster can be viewed at:

http://www.esr.cri.nz/SiteCollectionDocuments/ESR/PDF/FoodSafety/G%20positive%20phage%20poster.pdf

In an article describing the efficacy of one of these phages to control the growth of Listeria on ready-to-eat poultry products the authors even point out the likelihood of this phage belonging to the SPO1-like Listeria phages (Bigot et al. 2011).

There is compelling evidence that phages belonging to the P100 species are found globally and evidence supporting that this is likely true for New Zealand as well.

We therefore conclude that the product LISTEX does not constitute a novel organism not native to New Zealand.

References:

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