

25 September 2015
[23–15]

Call for submissions – Application A1111

Bacteriophage S16 & FO1a as a Processing Aid

FSANZ has assessed an Application made by Microcos B.V. to approve a preparation of two bacteriophages (S16 and FO1a), *Salmonalex*TM, (hereafter referred to as *Salmonella* phage) as a processing aid to reduce *Salmonella* spp. contamination in specific foods, and has prepared a draft food regulatory measure. Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

For information about making a submission, visit the FSANZ website at [information for submitters](#).

All submissions on applications and proposals will be published on our website. We will not publish material that is provided in-confidence, but will record that such information is held. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1991*. Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available on CD, rather than on the website.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at [information for submitters](#).

Submissions should be made in writing; be marked clearly with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website via the link on [documents for public comment](#). You can also email your submission directly to submissions@foodstandards.gov.au.

There is no need to send a hard copy of your submission if you have submitted it by email or via the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 6 November 2015

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions about making submissions or the application process can be sent to standards.management@foodstandards.gov.au.

Hard copy submissions may be sent to one of the following addresses:

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Supporting document

The following document which informed the assessment of this Application is available on the FSANZ website at

<http://www.foodstandards.gov.au/code/applications/Pages/A11111BacteriophageS16-F01asPA.aspx>

SD1 Risk assessment

Executive summary

All references to the *Australia New Zealand Food Standards Code* (the Code) in this assessment summary and related Supporting Document (SD) are to the revised Code which takes effect and replaces the current Code on 1 March 2016. This is because the gazettal of any draft variation is not expected until after this date, if approved by the FSANZ Board and no review of that decision is requested by Ministers, and FSANZ therefore considers it is unnecessary to amend the current Code.

FSANZ received an application (A1111) from Microeos B.V. on 13 March 2015, seeking to permit a *Salmonella* phage preparation (S16 and FO1a), *Salmonex*TM, (subsequently called *Salmonella* phage in this report) for use as a processing aid to control *Salmonella* spp. during post-slaughter processing of fresh meat and poultry products.

Salmonella is one of the most commonly reported causes of foodborne illness, with raw fresh meat and poultry often implicated as a source of infection. Fresh raw meat and poultry can be contaminated with *Salmonella* which can cause illness if meat is consumed undercooked or if cross contamination occurs during handling and preparation.

Bacteriophages are viruses that infect and break down bacterial cells. They are specific to the strains of bacteria they infect and are not pathogenic to plants, animals or humans. 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. They are not meant as a replacement for good hygienic practices nor as an alternative to approved and effective cleaning and sanitising agents generally used in the food industry.

The Applicant has provided evidence that the *Salmonella* phage which is the subject of this Application, is highly specific to *Salmonella* species and is for use during post-slaughter processing of raw meat. Further, use of the *Salmonella* phage should be viewed as an additional tool for control of *Salmonella* in food, supplementing Good Manufacturing Practices (GMP), Hazard Analysis Critical Control Points (HACCP) and other measures aimed at preventing *Salmonella* contamination, and should not be seen as a replacement of hygiene.

No permissions currently exist for the *Salmonella* phage in the table to section S18—9 in Schedule 18. Permission does exist for another phage preparation, *Listeria* phage P100, which is specific for *Listeria monocytogenes* and is permitted for use as a listericidal treatment on approved food for use of phage under conditions of GMP, in accordance with section S18—9.

Permitted processing aids also need to have an appropriate specification for identity and purity. No specification monographs for the *Salmonella* phage are within the references in sections S3—2 and S3—3 of Schedule 3. A soy peptone product is used during the manufacture of the *Salmonella* phage. Food manufacturers who use the *Salmonella* phage as a processing aid need to be aware of their responsibilities under subsection 1.2.3—4 should any residual soy product be present in the final food.

The risk assessment carried out for this Application concluded that the *Salmonella* phage was completely characterised and its use, as proposed by the Applicant, was technologically justified and safe. It was further concluded that the *Salmonella* phage is likely to maintain its efficacy (not develop reduced sensitivity to *Salmonella* spp.) provided appropriate GMP and Good Handling Practices are maintained during processing.

FSANZ therefore proposes to include specifications and permission for use of the *Salmonella* phage as a processing aid in the Code.

1 Introduction

1.1 The Applicant

The Applicant is Microeos B.V., a company specialising in supply of antibacterial products for human health and food safety.

1.2 The Application

FSANZ received an application (A1111) from Microeos B.V. on 13 March 2015, to permit a *Salmonella* phage preparation (S16 and FO1a), tradename Salmonex™, (subsequently called *Salmonella* phage in this report) for use as a processing aid aimed at controlling *Salmonella* spp. during post-slaughter processing of fresh meat and poultry products.

Salmonella is one of the most commonly reported causes of foodborne illness, with fresh raw meat and poultry often implicated as a source of infection. Fresh raw meat and poultry can be contaminated with *Salmonella* which can cause illness if meat is consumed undercooked or if cross contamination occurs during handling and preparation.

Meat is susceptible to *Salmonella* contamination during processing, with poultry meat more susceptible than other meat. Poultry processing is a highly automated industry in which many points exist for cross-contamination when *Salmonella*-positive birds enter the processing plant. To address the multiple points where birds may be contaminated, several antimicrobial controls are applied at various steps during processing. This multi-hurdle approach usually results in multiple antimicrobial interventions being used. Generally, sites where antimicrobials are applied include online reprocessing or inside/outside bird wash stages, the poultry chiller and post-chill applications where carcasses are disassembled.

Bacteriophages are viruses that infect and break down bacterial cells. They are specific to the strains of bacteria they infect and are not pathogenic to plants, animals or humans 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. They are not meant 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.

The Applicant states the *Salmonella* phage is highly specific to *Salmonella* species and for use during post-slaughter processing of raw meat. Further, the use of the *Salmonella* phage should be viewed as an additional tool for control of *Salmonella* in food, Good Manufacturing Practices (GMP), Hazard Analysis Critical Control Points (HACCP) and other measures aimed at the preventing *Salmonella* contamination, and should not be seen as a replacement for good hygiene.

1.3 The current Standard

Paragraph 1.1.1—10(4)(c) of the revised *Australia New Zealand Food Standards Code* (the Code), provides that a food for sale must not have, as an ingredient or a component, a substance that is used as a processing aid, unless expressly permitted. Section 1.1.2—13 defines the expression 'used as a processing aid'.

Section 1.3.3—11 affords the permission for processing aids that perform various technological functions with specific permissions in the table to section S18—9 in Schedule 18.

No permissions currently exist for the *Salmonella* phage in the table to section S18—9.

Permission does exist for another phage preparation, that being *Listeria* phage P100, which is specific for *Listeria monocytogenes* and is permitted for use as a listericidal treatment on approved food for use of phage under conditions of GMP, in accordance with section S18—9.

In accordance with section 1.1.1—15, all permitted processing aids must comply with relevant specifications which are set out in Schedule 3. No specifications for the *Salmonella* phage are listed in specifications under section S3—2 (Substances with specifications in primary sources) or section S3—3 (Substances with specifications in secondary sources). Therefore, specifications for the *Salmonella* phage are proposed to be included in Schedule 3.

1.3.1 International Standards

Codex Alimentarius does not list standards for either processing aids or bacteriophages. Individual countries regulate the use of processing aids and bacteriophages differently. A number of permissions for bacteriophages used as processing aids in foods are provided in international regulations.

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). In 2012, EFSA released an opinion on the safety and efficacy of using Listex P100™ to treat raw fish.

A number of Generally Recognized as Safe (GRAS) notifications have been made to the United States Food and Drug Administration (USFDA) for various *Salmonella* and *Listeria* bacteriophage preparations for use in foods.

1.3.1.1 *Salmonella* bacteriophages

In December 2013 GRAS Notice No. GRN468, submitted by the Applicant (Microcos B.V.) to the USFDA, received a 'no questions' notification for the use of bacteriophage preparation S16 and FO1a (Salmonalex™), as an antimicrobial to control *Salmonella* in meat and poultry, at up to 10⁸ plaque forming units (pfu) per gram of food. This is the same phage preparation and intended use as proposed in this Application.

Intralytix Inc., a competitor to Microcos B.V., also received a 'no questions' notification from the USFDA in February 2013 to GRAS Notice, No. GRN435 for use of a preparation containing six bacterial monophages specific to *Salmonella* (tradename SalmoFresh™) for use as an antimicrobial in certain poultry products, fish, shellfish, and fresh and processed fruits and vegetables at levels up to 10⁷ pfu/g.

1.3.1.2 *Listeria* bacteriophages

In 2014, the USFDA issued a 'no questions' notification to GRAS Notice No. GRN528 submitted by Intralytix Inc. The submission was for use of a preparation containing six bacterial monophages (LIST-36, IMSP-25, IMTA-34, IMT-57, IMTA-94 and IMTA-148) specific to *Listeria monocytogenes* (tradename ListShield™), for use as an antimicrobial to control *L. monocytogenes* in fish and shellfish, fresh and processed fruits, fresh and processed vegetables, and dairy products applied to food surfaces at levels up to 1 x 10⁶ pfu/g.

In 2012, FSANZ approved an application (Application A1045) submitted by the Applicant to this Application (Microcos B.V.), to permit the use of *Listeria* phage P100 (tradename Listex P100™) as a processing aid on approved foods for use of phage under conditions of GMP.

The product Listex P100™ is also approved for use in a number of other countries:

- The Dutch Ministry of Public Health permitted use of Listex P100™ as a processing aid for use on all foods in The Netherlands in July 2009.
- Listex P100™ is self-assessed GRAS in the USA in cheese (GRAS Notice No. GRN198 in 2006), and was extended to all food products susceptible to contamination with *L. monocytogenes* in 2007 (GRAS Notice GRN218), with labelling provisions. In 2011, USDA permitted its use as a processing aid on RTE meat and poultry products without labelling requirements.
- Health Canada issued a '*letter of no objection*' for use of Listex P100™ for use as a processing aid in several foods in 2010.

1.4 Reasons for accepting Application

The Application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2) of the FSANZ Act
- it related to a matter that might be developed as a food regulatory measure.

1.5 Procedure for assessment

The Application is being assessed under the General Procedure.

2 Summary of the assessment

2.1 Risk assessment

A risk assessment was conducted which considered the technological suitability, the potential hazards and any public health and safety issues of using the *Salmonella* phage to treat food. A brief overview of the assessment is provided below (refer to Supporting Document 1 (SD1) for full details).

The stated purpose for the *Salmonella* phage is as a processing aid to reduce *Salmonella* during post-slaughter processing of raw fresh meat and poultry. FSANZ investigated how the *Salmonella* phage performs its technological function when used as proposed by the Applicant. In assessing the technological function, both efficacy (ability to reduce numbers of *Salmonella* on application) and ongoing technological function (ability to *continuously* reduce bacterial numbers) were considered. Ongoing technological function was qualitatively assessed from the changes in *Salmonella* concentration throughout duration of the challenge studies provided by the Applicant. Efficacy was determined by statistical analysis of *Salmonella* concentrations between untreated and treated samples at different times.

Overall the *Salmonella* phage was found to be efficacious and does not have an ongoing technological function on raw fresh meat and poultry products. How the *Salmonella* phage is applied, the concentration of the phage used and the contact time, are all factors which would need consideration before use. The *Salmonella* phage is highly specific to *Salmonella* species and for use during post-slaughter processing of fresh meat.

Use of the *Salmonella* phage should be viewed as an additional tool for control of *Salmonella* in food, supplementing GMP, HACCP and other measures aimed at the preventing *Salmonella* contamination, and should not be seen as a replacement of good hygiene. The *Salmonella* phage is likely to maintain its efficacy (not develop reduced sensitivity to *Salmonella* spp.) provided appropriate GMP and Good Handling Practices (GHP) are maintained during processing.

The *Salmonella* phage is unlikely to pose any health risk when used as intended to treat fresh raw meat and poultry. Further, the proposed use of the *Salmonella* phage as a processing aid to reduce the levels of *Salmonella* during post-slaughter processing of raw fresh meat and poultry, is technologically justified in the form and prescribed amounts, and demonstrated to be effective. The *Salmonella* phage is completely characterised and there is no ongoing technological function performed when used as intended.

2.2 Risk management

The conclusions of the risk assessment were that the use of the *Salmonella* phage was safe for use and technologically justified for the intended purpose. FSANZ has considered the risk management matters relevant to the Application.

2.2.1 Specification for *Salmonella* phage preparation (S16 and FO1a)

There are no specifications for bacteriophages, or specifically *Salmonella* phage, in any of the primary or secondary references for specifications or in Schedule 3 – Identity and Purity. A proposed specification has been prepared and is included in the draft variations at Attachment A.

Consistent with specifications written for *Listeria* phage P100, specifications for lead and arsenic are addressed by the requirements of section S3—4. The Applicant has demonstrated that the *Salmonella* phage is manufactured according to GMP.

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

2.2.2 Labelling considerations

Soy peptone is used as a medium in the production of the *Salmonella* phage. A soy peptone-salt buffer is used to elute the bound phages from the chromatography column. Soybean products are identified as substances requiring declaration due to section 1.2.3—4 of the Code if present in a food for sale. Food manufacturers who use the *Salmonella* phage as a processing aid need to be aware of their responsibilities under section 1.2.3—4.

2.3 Risk communication

FSANZ has developed and applied a basic communication strategy to this Application.

2.3.1 Consultation

Consultation is a key part of FSANZ's standards development process. The process by which FSANZ considers standard development matters is open, accountable, consultative and transparent. Public submissions are sought to obtain the views of interested parties on the Application and the impacts of regulatory options. All calls for submissions are notified via the Food Standards Notification Circular, media release, FSANZ's social media tools and Food Standards News.

The draft variation will be considered for approval by the FSANZ Board taking into account public comments received from this call for submissions.

The Applicant, individuals and organisations that make submissions on this Application will be notified at each stage of the assessment. Subscribers and interested parties are also notified via email about the availability of reports for public comment.

Following consultation, the FSANZ Board will consider the proposed variation taking into account comments received through submissions. If the draft variation to the Code is approved by the FSANZ Board, that decision will be notified to the Australia and New Zealand Ministerial Forum on Food Regulation (the Forum). If the decision is not subject to a request for a review, the Applicant and stakeholders, including the public, will be notified of the gazettal of the variation to the Code in the national press and on the FSANZ website.

2.3.2 World Trade Organization (WTO)

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

There are no relevant international standards and amending the Code to allow *Salmonella* phage as a processing aid is unlikely to have a significant effect on international trade. Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Application of Sanitary and Phytosanitary Measures Agreement was not considered necessary.

2.4 FSANZ Act assessment requirements

When assessing this Application and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters in section 29 of the FSANZ Act:

2.4.1 Section 29

2.4.1.1 Cost benefit analysis

FSANZ is required to consider the impact of various regulatory and non-regulatory options on all sectors of the community, especially relevant stakeholders who may be affected by this Application. The benefits and costs associated with the proposed amendments to the revised Code have been considered using regulatory impact principles. The level of analysis is commensurate with the nature of the Application and significance of the impacts.

The Office of Best Practice Regulation, in a letter dated 24 November 2010 (reference 12065), provided a standing exemption from the need to assess if a Regulation Impact Statement is required for applications relating to processing aids as they are machinery in nature and their use is voluntary.

However, FSANZ has undertaken a limited impact analysis.

Two regulatory options were considered:

- (1) prepare a draft variation to the revised Code to permit the use of *Salmonella* phage as a processing aid and develop a specification
- (2) reject the Application.

A consideration of the costs and benefits of the regulatory options is not intended to be an exhaustive, quantitative economic analysis of the options and, in fact, most of the effects that are considered cannot be assigned a dollar value. Rather, the assessment seeks to highlight the qualitative effects on broad areas such as trade, consumer information and compliance.

Option 1 – Prepare a draft variation

Sector	Costs or benefits to sector
Consumers	There should be no measurable impact or costs on consumers, but there may be benefits from control of <i>Salmonella</i> during processing which may reduce a risk factor for foodborne illness.
Industry	There are benefits to the meat processing industry in helping to control <i>Salmonella</i> contamination. Australian and New Zealand meat processors may benefit from having another option to use in controlling <i>Salmonella</i> . The risk assessment conclusions provide evidence that there are no safety risks from the use of this phage preparation as intended in their food safety controls for managing <i>Salmonella</i> .
Governments	There are no costs or benefits to governments associated with this option.

Option 2 – Reject the Application

Sector	Costs or benefits to sector
Consumers	There are no benefits or costs to consumers of this option.
Industry	There may be costs by not allowing industry the option to use new technology to help control <i>Salmonella</i> during processing.
Governments	There are no direct impacts on government agencies.

FSANZ considered that Option 1, to permit and develop a specification for *Salmonella* phage as a processing aid, is the preferred option and has prepared draft variations to the revised Code.

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

2.4.1.2 Other measures

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure developed or varied as a result of the Application.

2.4.1.3 Any relevant New Zealand standards

Schedules 3 and 18 apply in New Zealand.

2.4.1.4 Any other relevant matters

There are no other relevant matters.

2.4.2. Subsection 18(1)

FSANZ has also considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

2.4.2.1 Protection of public health and safety

FSANZ has undertaken a safety assessment (SD1) and concluded that there are no public health and safety concerns related to use of *Salmonella* phage as a processing aid.

2.4.2.2 The provision of adequate information relating to food to enable consumers to make informed choices

No issues have been identified for this Application relevant to this objective. The labelling requirements for this processing aid are discussed in Section 2.2.2 – Labelling considerations.

2.4.2.3 The prevention of misleading or deceptive conduct

No issues were identified for this Application relevant to this objective.

2.4.3 Subsection 18(2) considerations

FSANZ has also had regard to:

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

FSANZ has used the best available scientific evidence to conduct the risk analysis which is provided in SD1. The Applicant submitted a dossier of evidence as part of their Application. Other technical information including scientific literature was also used in assessing the Application.

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

Section 1.3.1 describes the current permissions for various bacteriophages in different countries. The attributes of using bacteriophages as a component of food safety management systems to control bacterial contamination on foods has been described.

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

The food industry will make their own economic decisions, taking account of costs and benefits of using phage as part of their hurdle technology to control *Salmonella* to determine if it benefits their business.

- **the promotion of fair trading in food**

The *Salmonella* phage has been permitted and assessed as safe in other countries. FSANZ's own risk analysis has confirmed this finding. It is therefore appropriate that the local Australian and New Zealand food industries have access to the same technology which may have benefits to industry and consumers.

- **any written policy guidelines formulated by the Ministerial Council¹**

The Addition to Food of Substances other than Vitamins and Minerals² 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
- the substance is added in a quantity and a form which is consistent with delivering the stated purpose
- no nutrition, health or related claims are to be made in regard to the substance.

FSANZ has determined that permitting the use of *Salmonella* phage as a processing aid is consistent with the specific order policy principles for 'Technological Function'.

3 Draft variation

The draft variation to the revised Code and related draft explanatory statement are at Attachment A. The variation is intended to take effect on gazettal.

An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislative Instruments (FRLI).

4 References

US FDA (2013). GRAS Notice No. GRN 468 [Preparation containing the bacterial monophages, Fo1a and S16, specific to *Salmonella*]. Submitted by Microcos B.V. to U.S. Food and Drug Administration (US FDA), on 30 April 2013. Releasable dossier and Agency Response Letter available at this link http://www.accessdata.fda.gov/scripts/fdcc/?set=GRASNotices&id=468&sort=GRN_No&order=DESC&startrow=1&type=basic&search=468 Accessed on 7 September 2015

US FDA (2013). GRAS Notice No. GRN 435 [Preparation consisting of six bacterial monophage specific to *Salmonella enterica* (monophage cocktail)]. Submitted by Intralytix, Inc. to U.S. Food and Drug Administration (US FDA), on 6 July, 2012. Releasable dossier and Agency Response Letter available at this link http://www.accessdata.fda.gov/scripts/fdcc/?set=GRASNotices&id=435&sort=GRN_No&order=DESC&startrow=1&type=basic&search=435 Accessed on 7 September 2015

US FDA (2013). GRAS Notice No. GRN 528 [Preparation containing six bacterial monophages (LIST-36, LMSP-25, LMTA-34, LMTA-57, LMTA-94 and LMTA-148) specific to *Listeria monocytogenes*]. Submitted by Intralytix, Inc to U.S. Food and Drug Administration (US FDA), on 31 July 2014. Releasable dossier and Agency Response Letter available at this link http://www.accessdata.fda.gov/scripts/fdcc/?set=GRASNotices&id=528&sort=GRN_No&order=DESC&startrow=1&type=basic&search=528 Accessed on 7 September 2015

¹ Now known as the Australia and New Zealand Ministerial Forum on Food Regulation (convening as the Australia and New Zealand Food Regulation Ministerial Council)

² <http://www.foodstandards.gov.au/code/fofr/fofrpolicy/pages/default.aspx>

US FDA (2013). GRAS Notice No. GRN 198 [Bacteriophage P100 preparation from *Listeria innocua*]. Submitted by EBI Food Safety B.V. to U.S. Food and Drug Administration (US FDA), on 20 April 2006. Releasable dossier and Agency Response Letter available at this link http://www.accessdata.fda.gov/scripts/fdcc/?set=GRASNotices&id=198&sort=GRN_No&order=DESC&startrow=1&type=basic&search=198 Accessed on 7 September 2015

US FDA (2013). GRAS Notice No. GRN 218 [Bacteriophage P100 preparation from *Listeria innocua*]. Submitted by EBI Food Safety B.V. to U.S. Food and Drug Administration (US FDA), on 17 December 2006. Releasable dossier and Agency Response Letter available at this link http://www.accessdata.fda.gov/scripts/fdcc/?set=GRASNotices&id=218&sort=GRN_No&order=DESC&startrow=1&type=basic&search=218 Accessed on 7 September 2015

EFSA (2009). “The use and mode of action of bacteriophages in food production”, Scientific Opinion of the EFSA Panel on Biological Hazards (BIOHAZ) – EFSA Journal 2009:1076 <http://www.efsa.europa.eu/en/efsajournal/pub/1076>

Attachments

- A. Draft variation to the revised *Australia New Zealand Food Standards Code*
- B. Draft Explanatory Statement

Attachment A – Draft variation to the revised *Australia New Zealand Food Standards Code*



Food Standards (Application A1111 – Bacteriophage S16 & FO1a 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 variation commences on the date specified in clause 3 of this variation.

Dated [To be completed by Standards Management Officer]

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

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC **XX on XX Month 20XX**. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

1 Name

This instrument is the *Food Standards (Application A1111 – Bacteriophage S16 & FO1a as a Processing Aid) Variation*.

2 Variation to a Standard in the *Australia New Zealand Food Standards Code*

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

3 Commencement

This instrument commences on gazettal.

Schedule

[1] **Schedule 3** is varied by

[1.1] inserting in the table to subsection S3—2(2) in alphabetical order

“

Salmonella phage preparation (S16 and FO1a) section S3—33

”

[1.2] inserting after section S3—32

“S3—33 **Specifications for *Salmonella* phage preparation (S16 and FO1a)**

(1) In this section:

a preparation means a *Salmonella* phage preparation (S16 and FO1a).

Salmonella phage preparation (S16 and FO1a) means a solution of a 1:1 blend of *Salmonella* phage S16 and *Salmonella* phage FO1a.

(2) *Salmonella* phage S16 in a preparation must comply with the specification in subsection (4).

(3) *Salmonella* phage FO1a in a preparation must comply with the specification in subsection (5).

(4) The biological classification for *Salmonella* phage S16 in a preparation is the following:

- (a) order—Caudavirales;
- (b) family—Myoviridae;
- (c) genus—T4-like;
- (d) species—*Salmonella* phage S16;
- (e) GenBank Accession Number—HQ331142

(5) The biological classification for *Salmonella* phage FO1a in a preparation is the following:

- (a) order—Caudavirales;
- (b) family—Myoviridae;
- (c) genus—FelixO1-like;
- (d) species—*Salmonella* phage FO1a;
- (e) GenBank Accession Number—JF461087.”

[2] **Schedule 18** is varied by inserting in the Table to section S18—9 in alphabetical order

“

Salmonella phage preparation (S16 and FO1a) Reduce *Salmonella* species on or in raw meat during processing. GMP

”

Attachment B – Draft Explanatory Statement

1. Authority

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

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

FSANZ accepted Application A1111 which seeks approval for a preparation of two bacteriophages (S16 and FO1a) (tradenname *Salmonex*TM) as a processing aid to reduce *Salmonella* contamination in specific foods. The Authority considered the Application in accordance with Division 1 of Part 3 and has proposed a draft Variation.

2. Purpose

The Authority has proposed that *Salmonella* phage preparation (S16 and FO1a) be added to the list of approved processing aids with miscellaneous technological functions for use in specific foods. The table to section S18—9 in Schedule 18 lists permissions for these processing aids, as well as the foods and levels which are allowed. An entry for *Salmonella* phage preparation (S16 and FO1a) will be included for use in or on raw meat during processing at levels up to Good Manufacturing Practice (GMP). A specification stating what the preparation is composed of will also be included into Schedule 3.

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 Application A1111 will include one round of public consultation following an assessment and the preparation of a draft variation and associated report.

A Regulation Impact Statement was not required because the proposed variations to Schedule 18 and Schedule 3 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. Variation

Item [1] varies Schedule 3 of the Code.

Item [1.1] amends the table to subsection S3—2(2) by inserting a reference to *Salmonella* phage preparation (S16 and FO1a) and to new subsection S3—33. This in effect provides that the specification listed in new subsection S3—33 is the specification for *Salmonella* phage preparation (S16 and FO1a).

Item [1.2] new subsection S3—33 into Schedule 3. The new subsection provides a compositional specification for *Salmonella* phage preparation (S16 and FO1a) (S3—33) by reference to the biological classification of its component phages

Item 2 varies Schedule 18 of the Code. The Item amends the table to section S18—9 to include an entry for *Salmonella* phage preparation (S16 and FO1a) in the list of approved processing aids with miscellaneous technological functions. The new entry states that the phage preparation can be used for the technological purpose of reducing *Salmonella* species or in raw meat during processing. The entry also states that the maximum permitted level is that which is consistent with Good Manufacturing Practice.