



1 November 2011

Project Officer Application A1045  
PO Box 10559  
The Terrace  
WELLINGTON 6036

FS350-117-1045

Dear Sir/Madam

## **Application A1045 – Bacteriophage Preparation P100 as a Processing Aid – 1st Assessment Report**

Thank you for the opportunity to comment on this application. The Ministry of Agriculture and Forestry (MAF) has the following comments to make.

### **Comments on questions to be answered (Section 4)**

*Is the P100 bacteriophage preparation suitably well characterised?*

We agree that the product should always be called P100, not a bacteriophage preparation. We note that P100 is a product with a single phage and that similar products with other phages would be subject to further application and risk assessment. This is in contrast to phage preparations for *E. coli* O157:H7 which contain multiple phage, allowing a manufacturer to improve the product for example by substituting alternative phage to accommodate geographical differences among host strains.

In Section 6.2, it is stated in the last paragraph that *The Applicant has also advised that they will continuously work with users to monitor phage resistance development and to update the P100 preparation as required to maintain efficacy.* In MAF's view, further detail of methods for achieving this should be provided. Some methods for manipulating phage preparations may alter the technological function or safety profile of the product and hence should be considered in the scope.

MAF notes that data on the stability of P100 during storage or on the food product has not been provided, although some information on stability in food has been alluded to (in the absence of temperature information). This data is important both for determining whether the preparation can achieve its stated technological purpose and whether it conforms to the definition of a processing aid.



**Ministry of Agriculture and Forestry**  
Te Manatū Ahuwhenua, Ngāherehere  
Pastoral House, 25 The Terrace, PO Box 2526, Wellington, 6140, New Zealand  
Telephone: 0800 00 83 33, Web: [www.maf.govt.nz](http://www.maf.govt.nz)



*Does the P100 preparation achieve its stated technological purpose?*

- *Has the technological need been articulated clearly?*
- *Is the preparation added in a quantity and form which is consistent with delivering the stated purpose?*

The use of bacteriophage preparation P100 as part of a validated, audited food safety management system for the control of *Listeria monocytogenes* may perform a useful adjunct role in assuring the safety of non-liquid ready-to-eat foods.

- *Can development of resistance render the P100 preparation ineffectual?*

MAF believes that the risk of resistance development is negligible as the host range is so specific. Resistance can “occur” to phages, although this should be called strain specificity rather than resistance. New phages are normally added to cocktails to cover this. However, it is unlikely that resistance will “develop” in previously susceptible isolates.

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

- ☐ *Are there potential allergens present in the P100 preparation?*
- ☐ *Are there toxicological safety issues?*

MAF has no comments at this time.

## **Implementation issues to be addressed**

The application specifies that prevention of reintroduction to processing plants is a key measure to minimise the likelihood of development of resistance. The practicality of managing/regulating this needs to be considered, including

- in cases where re-processing of product may otherwise be undertaken by industry/ ordered by regulators in response to an identified *Listeria* contamination event (regulators are unlikely to be aware that P100 has been applied to the product)
- when RTE foods are used as ingredients in other products subsequent parts of the food chain may not be aware that P100 has been applied.

## **EPA considerations**

New Zealand's Environmental Protection Authority (EPA), formerly ERMA, regulates new organisms (plants, animals, genetically modified organisms) and hazardous substances and chemicals and as such would need to be consulted should any phage material be considered a new organism. Similarly there may be biosecurity implications and MAF biosecurity may require consultation.

## **Comments on classification as a processing aid, and labelling implications**

The main evidence for non-ongoing technical function (and hence definition of the product as a processing aid) appears to relate to the limited mobility of phage in non-liquid products. Ongoing activity was reported in chocolate milk, and this has been attributed to the liquid nature of the food matrix. In the

absence of evidence of inactivation on product, it must be assumed that P100 would continue to be active against drop-in pathogens after the initial application.

It is only in section 5.3 of the Risk Assessment Report that there is any indication that the intended use is in product immediately prior to packaging. In the absence of evidence to the contrary, the phage preparation may be assumed to perform an ongoing technological role if no evidence of inactivation is provided. Unless the food is packaged the phage may be active against susceptible drop-in contaminants. We note that the data analysed by FSANZ (Guenther *et al.* 2009 section 5.2.2.1(c) of the RA Report) covers a single phage concentration that is lower than the recommended rate for use, and comes with a disclaimer that the use of higher concentrations may change the findings for the phage *Listeria monocytogenes* Scott A in smoked salmon with respect to the potential for assessing ongoing technological function.

We note that Standard 1.3.1 Schedule 5 lists *bacteriophage control agent* as a sub-class of the functional class "preservative". FSANZ may need to review the appropriateness of this entry. Furthermore, there may be cases where the use of phage is more appropriately considered a food additive use, for example in liquid foods.

MAF notes that the statement in Section 6.6.2 that *there is unlikely to be any phage preparation left on treated food* is likely to be incorrect as the phage is present but will be largely inactive due to increasingly lower levels and being immobile having already cleared any pathogens in contact. Consequently, ongoing activity is not ensured.

Yours sincerely

Signed pp David Roberts

Jenny Reid  
**Manager Food Safety**

