NSW Food Authority

# Application A1045
# BACTERIOPHAGE PREPARATION P100 AS A PROCESSING AID

**Major Procedure**

## Summary

The NSW Food Authority generally supports the use of novel technology to provide additional hurdles for producers of ready-to-eat products to control *Listeria monocytogenes*.

The Authority considers the appropriate use of such technology could potentially minimise the presence of *L. monocytogenes* in finished product, when used in conjunction with Good Manufacturing Practice (GMP). This could potentially reduce the number of recalls of finished product due to the presence of *L. monocytogenes* and protect public health from the risk of listeriosis.

## Specific Issues

The Authority is satisfied that the application of the P100 phage preparation does not affect the organoleptic qualities of the food and does not pose a risk to human health.

## Approvals for use in other countries

The Authority notes the following:

- letter of no objection from Health Canada for use of Listex P100 as a processing aid within the range 1 x $10^7$ to 1 x $10^9$ phage per gram of treated food
- GRAS status given to Listex P100 by the US Food and Drug Administration; and
- the approval by the US Food Safety and Inspection Service (FSIS) for use as a processing aid in meat and poultry products. The assessment by the FSIS was that the phage preparation provides only a momentary antimicrobial effect on treated product, is present in the finished product at insignificant levels, and there is no residual activity, even if the products were to be recontaminated with *L. monocytogenes*.

## Ongoing technological function

The application to use P100 as a processing aid, rather than a food additive, raises some interesting points. The scope of application A1045 is limited to 'non-liquid foods' – which are not defined in the Food Standards Code.

Although it is acknowledged that active phage numbers decline from the moment of application, it appears from data supplied by the applicant that the highest reduction is obtained after approximately 6-24 hours. After which time, any surviving cells of *L. monocytogenes* are able to grow as normal.

The applicant appears to indicate that there is ongoing technological function in liquid foods. As such, it is unclear whether an ongoing technological function would be

performed in a solid food where liquid may also occur in the pack (eg deli meats + exudate/purge/cook-out).
In addition, if a further application were to be made in the future for use of P100 in liquid foods then it would need to be classified as a food additive.
The Authority believes that there is potential for this to cause confusion in the food industry and for the consumer – as labelling requirements may vary depending on the food it is used in.

If the application of P100 is approved as a processing aid - by definition there is no technological function performed in the final food – the Authority believes that manufacturers of RTE products should be made aware that, should *L. monocytogenes* be detected in a treated product where Listex P100 has been applied, the use of the phage will not by itself move the food into the category of 'product does not support the growth of *L. monocytogenes*'. As such, an allowable limit of 100 cfu/g of *L. monocytogenes* would not apply and any detection of *L. monocytogenes* in finished product may be subject to recall.

It is unclear whether other preservative, salts and cures commonly used in RTE meats have an effect on the rate of inactivation of the phage and therefore the efficacy in reducing the numbers of *L. monocytogenes*.

**Incorporation of P100 use into food safety program**
The Authority agrees with the applicant that this processing aid is only to be used as an adjunct to existing control measures and the importance of good manufacturing practice (GMP) continues to be emphasised for control of *L. monocytogenes*.

The Authority agrees with the position of the US FSIS, where it notes that the use of the phage preparation as a processing aid would need to be included into a HACCP-based food safety program, with the method of applying the phage incorporated into standard operating procedures (SOPs). The effectiveness of the procedure for applying the phage preparation to the food should be validated under in-plant conditions and verified on an on-going basis. This may require ongoing technical support from the applicant for the use of the processing aid

**Phage resistance**
While it appears that the development of phage resistance is a small problem, it is stated that the applicant intends to monitor any *L. monocytogenes* isolates for such resistance. No details are provided and the Authority considers that further information is required from the applicant on how phage susceptibility will be monitored in food processing facilities using the P100 preparation.

In addition, it is not clear how the preparation may be 'updated' should phage resistance be detected. If this update were to be through the use of a different phage preparation, then there is an issue about whether this should be subject to another approval. It is noted that the Letter of no objection from Health Canada dated September 3, 2010 states "*This letter of no objection applies only to the preparation Listex that contains that phage P100 strain. Any change in the composition of phages of the preparation will render this letter void. Should you wish to modify the composition and specifications of the Listex P100 preparation we would expect a new submission in support of a new request of use*". In the first assessment report to A1045 it is stated that the specification would permit 'similar' preparations which would permit the phage manufacturer to modify the P100 preparation. This appears to be less stringent than the requirements employed by Health Canada and the Authority would like FSANZ to clarify the intent.

## Policy guidelines

The Authority believes that the application has met the requirements of the policy guidelines for the addition to food of substances other than vitamins and minerals in that:

- The purpose for adding the substance has been articulated clearly (reduce the number of *L. monocytogenes* in RTE food products)
- The addition of the substance is safe for human consumption
- The amounts added are consistent with achieving the technological function; and
- The substance will be added in a quantity and a form which is consistent with delivering the stated purpose
- No nutrition, health or related claims will be made on the use of the phage preparation.

## ENDS

**The views expressed in this submission may or may not accord with those of other NSW Government agencies. The NSW Food Authority has a policy which encourages the full range of NSW agency views to be submitted during the standards development stages before final assessment. Other relevant NSW Government agencies are aware of and agree with this policy.**