

**Comments from Dairy Food Safety Victoria and the Department of Health, Victoria  
27 April 2012**

Dairy Food Safety Victoria (DFSV) and the Department of Health, Victoria (DH) welcome the opportunity to make comment on Application A1045 to permit the use of a bacteriophage (*Listeria* phage) preparation Listex P100 as a processing aid in response to FSANZ's second call for submissions.

DFSV and DH refer FSANZ to the European Food Safety Authority's (EFSA) Scientific Opinion (the 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):2615. Adopted 08 March 2012). That opinion includes a number of statements and conclusions that raise concerns or that need to be reconciled with those made by FSANZ.

In the EFSA opinion, data of studies considered indicate that Listex P100 is listericidal on inoculated catfish and salmon samples. However, those data do not allow definitive conclusions on efficacy in reducing *L.monocytogenes* counts on raw fish nor on its impact on *L.monocytogenes* contamination levels in the finished product. **This raises the question on the need to produce data for the efficacy of Listex P100 for each specific product it is intended to be applied to and not to rely on work conducted using similar bacteriophage preparations.**

In addition, DFSV and DH make the following observations and suggestions from the opinion in relation to the FSANZ report:

- It was not possible to estimate the potential listeriosis risk reduction by treating raw fish with Listex P100.
- Tests to investigate potential development of resistance or reduced susceptibility to biocides and key therapeutic antimicrobials following the use of Listex P100 are recommended.
- The continuous effectiveness of Listex P100 against *L.monocytogenes* and the potential for selection and dominance of strains naturally resistant to P100 should be monitored.
- The data were not adequate to allow firm conclusions on persistence or activity of P100 in stored fish. The persistence or activity of P100 as well as potential changes in *L.monocytogenes* counts should be evaluated during fish storage.

In its report (2<sup>nd</sup> call for submissions, 16 March 2012, page 6) FSANZ states that "[t]he 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. However, from the opinion, no conclusions could be made on the fate of the bacteriophage P100 and it is possible that the phages in fact remain active. This is a critical point in determining whether Listex P100 is a processing aid or a food additive. This becomes more problematic if it were to be classified as a processing aid in solid foods but as a food additive in liquid foods.

A further issue that does not appear to have been addressed is the potential for phages to be released from the surface of solid foods due to syneresis or condensate.

In light of these issues, DFSV and DH believe that it is critical that FSANZ adequately addresses the concerns and issues raised in the EFSA opinion as this would be the first

bacteriophage preparation to be approved in Australia/NZ, and the current proposal to treat P100 as a processing aid would mean that there would be no disclosure of its presence in food.