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3.1.1 Executive Summary

This application is for Salmonalex™, a bacteriophage based solution, aimed at killing *Salmonella* during post-slaughter processing of fresh meat and poultry products.

OzFoodNet, the food-borne disease surveillance network operating in Australia, undertook a study to estimate the amount of food-borne gastroenteritis in a typical year. This study estimated that in a typical year (around the year 2000) there were approximately 92,000 total cases of salmonellosis (95% credible interval 26,000-158,000) (Hall et al, 2005). The report also estimated that the proportion of the total cases that could be attributed to food was estimated to be 87% or 81,000 (95% credible interval 23,000-138,000).

Poultry is one of the implicated foods in *Salmonella* outbreaks. While precise numbers of poultry associated salmonellosis cases in Australia do not exist, the high prevalence of *Salmonella* on chicken meat and overlap in serovars found on meat and in human cases proves that poultry meat is a major source of introducing *Salmonella* into Australian households and indicates that poultry meat is likely to be a major contributing factor in human salmonellosis (Fearnley et al, 2011).

In Australia, raw poultry meat purchased by the consumer is very likely to be contaminated with *Salmonella* (43%, with 13% being non- Sofia *Salmonella* serovars) (FSANZ 2010). The higher the prevalence and concentration of this bacteria being present on raw poultry, the greater the likelihood these pathogens could be present at the point of consumption and therefore a greater likelihood of illness occurring.

Raw poultry contaminated with *Salmonella* can cause illness if the poultry meat consumed is undercooked or contamination from the raw poultry is transferred to cooked poultry or other food that is ready-to-eat. Cross contamination between raw and ready-to-eat food is of particular concern, as only small numbers of the bacteria are needed to cause human illness.

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

Important attributes of bacteriophages include:

- they kill only *bacterial* target cells (no impact on plant or animal cells);
- they do not cross species or genus boundaries; therefore they will not affect desired bacteria in foods (e.g., starter cultures for cheese and sausages), and commensals in the gastrointestinal tract, or accompanying bacterial flora in the environment;
- they are composed entirely of proteins and DNA, so their breakdown products consist exclusively of amino acids and nucleotides, both of which are present in abundance in food products.

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Bacteriophages thus are not xenobiotics, and, unlike antibiotics and antiseptic agents, their introduction into, and distribution within a given environment can 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 micro-organisms 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 dairy and meat products, more than 10^8 viable phages per gram are often present (Kennedy and Bitton, 1984). It is a fact that phages are routinely consumed with our food in high numbers. Moreover, phages are also normal commensals of humans and animals, and are especially abundant in the gastrointestinal tract (Breitbart, 2003).

In conclusion, bacteriophages are known to be harmless for all other organisms and are species-specific" (often even specific for only a limited number of strains within this species).

In order to counteract *Salmonella* contamination problems, Micreos has developed a phage product which is highly specific for *Salmonella*; a bacteriophage preparation with the trade name SALMONELEX™.

This dossier contains all available data with regard to this product.

The bacteriophage preparation with its intended use for control of *Salmonella* on fresh poultry and meat product is:

- a liquid culture of two specific bacteriophages
- is effective against *Salmonella* as shown in by efficacy data presented in Appendix 1
- demonstrates a broad spectrum killing of *Salmonella* as presented in Appendix 2
- rapidly disintegrates into amino acids and nucleotides which are naturally present in abundance in food products,
- results in negligible amounts of residuals (amino acids and nucleotides)
- has no technical effect in the finished food

Based on these features we consider SALMONELEX™ to be a processing aid.

Regulation concerning processing aids is laid down in 1.3.3 "Processing Aids" of the Food Standards Code. SALMONELEX™ falls within the scope of a processing aid, as defined by the definitions in Standard 1.3.3 but is not listed in the clauses. To get an approval for a new processing aid and a change in Standard 1.3.3, an application has to be made to the FSANZ.



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For that reason this dossier has been prepared along the lines as laid down in the Food Standards Australia New Zealand document of 1 September 2013: "Food Standards Australia New Zealand Application Handbook".