

APPLICATION – EXECUTIVE SUMMARY

OCTOBER 2016

TO:

FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

IN RELATION TO:

APPLICATION FOR APPROVAL OF USE OF POLYSORBATE
20 AS A FOOD ADDITIVE IN STANDARD 1.3.1 – FOOD
ADDITIVES.

EXECUTIVE SUMMARY

The purpose of this application is to request an amendment to Schedule 16 – Types of substances that may be used as food additives of the *Australia New Zealand Food Standards Code* (the Code) to permit the use of Polyoxyethylene (20) Sorbitan Monolaurate or Polysorbate 20 (Additive 432) (hereafter referred to as Polysorbate 20) as a food additive (emulsifier) at GMP.

Earlee Products Pty Ltd (Earlee) intends to use Polysorbate 20 as an emulsifier at levels of less than 0.05% in the final food product as a functional component in a surface spray or dipping solution for cooked processed meats/small goods and processed fish and fish products. Polysorbate 20 is required to fulfil the function of a dispersal agent for the natural antimicrobial agents present in the Applicant's dips and sprays used in processed raw and whole, comminuted meat, poultry, seafood and game products to enhance the shelf life by inhibiting the growth of background standard bacteria (spoilage) but also pathogenic bacteria such as *Staphylococcus aureus*, *E. coli*, and *L. monocytogenes*. Through extensive product development trials, the Applicant has determined that Polysorbate 20 is the only emulsifier that satisfied all their necessary criteria.

Polysorbate 20 has the following monographs of identity:

- (a) Food Chemicals Codex (FCC) has published a monograph on Polysorbate 20; and
- (b) JEFCA has published a monograph on Polysorbate 20.

Polysorbate 20 is permitted in the Codex General Standard for Food Additives (GSFA, Codex STAN 192-1995) which sets forth the conditions under which permitted food additives may be used in all foods, whether or not they have previously been standardized by Codex. Polysorbate 20 is also approved in other countries/regions such as the USA, Europe, Japan and Singapore.

Other Polysorbates are currently permitted to be added to food in Australia and New Zealand at GMP levels under the following Schedules of the Australian New Zealand Food Standards Code (the Code) as follows:

Additive	Standard	Permitted Products	Level permitted
<p style="text-align: center;">431</p> Polysorbate 40 - Polyoxyethylene (40) stearate	Schedule 15	Dried milk, milk powder, cream powder (1.5); and Wine, sparkling wine and fortified wine (14.2.2)	GMP GMP
<p style="text-align: center;">433</p> Polysorbate 80 - Polyoxyethylene (20) Sorbitan Monooleate	Schedule 16	Additive permitted at GMP	GMP
<p style="text-align: center;">435</p> Polysorbate 60 - Polyoxyethylene (20) Sorbitan Monostearate	Schedule 16	Additive permitted at GMP	GMP
<p style="text-align: center;">436</p> Polysorbate 65 - Polyoxyethylene (20) Sorbitan Tristearate	Schedule 16	Additive permitted at GMP	GMP

The current ADI of 25mg/kg bodyweight/day applicable to Polysorbate 20 is a group ADI that applies to all five polysorbates (20, 40, 60, 65 and 80). It was established by JECFA in 1974.

In 2015, the EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS) re-evaluated the polysorbates and also established a group ADI of 25 mg/kg bw/day for polysorbates 20, 40, 60, 65 and 80.

The EFSA reevaluation concluded that:

- The acute oral toxicity of all polysorbates was low.
- Taking into account the overall information on structure–activity relationships, polysorbates do not give rise to concerns for genotoxicity.
- Available long-term oral studies did not fulfil the requirements of current standards but long-term studies in rats indicated a NOAEL of 5 % in the diet (approximately 2,500 mg/kg bw/day) based on an oral carcinogenicity study with Polysorbate 80 (NTP, 1992).
- Applying an uncertainty factor of 100, EFSA established a group ADI of 25 mg/kg bw/day for polysorbates 20, 80, 40, 60 and 65 (E 432, E 433, E 434, E 435 and E 436, respectively). This is consistent with the ADI established previously by JECFA (1974).

The use of Polysorbate 20 in foods at the levels proposed by the Applicant is not expected to lead to any adverse health effects when consumed at the intended levels in the foods described within the application.