

24 July 2018

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Dear Sir/Madam

Attached are the comments that the New Zealand Food & Grocery Council wishes to present on the *Call for submissions – Application A1137 Polysorbate 20 as a Food Additive*.

Yours sincerely



***Call for submissions – Application A1137  
Polysorbate 20 as a Food Additive***

**Submission by the New Zealand Food & Grocery  
Council**

**24 July 2018**

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## NEW ZEALAND FOOD & GROCERY COUNCIL

1. The New Zealand Food & Grocery Council (“NZFGC”) welcomes the opportunity to comment on the ***Call for submissions – Application A1137 Polysorbate 20 as a Food Additive.***
2. NZFGC represents the major manufacturers and suppliers of food, beverage and grocery products in New Zealand. This sector generates over \$34 billion in the New Zealand domestic retail food, beverage and grocery products market, and over \$31 billion in export revenue from exports to 195 countries – some 72% of total merchandise exports. Food and beverage manufacturing is the largest manufacturing sector in New Zealand, representing 44% of total manufacturing income. Our members directly or indirectly employ more than 400,000 people – one in five of the workforce.

### The Application

3. Earlee Products Pty Ltd (Brisbane, Australia) applied for permission in the Australia New Zealand Food Standards Code (the Food Standards Code) for a food additive, polyoxyethylene (2) sorbitan monolaurate, known as polysorbate 20, in October 2016. The intended use was for processed meat products and processed fish and fish products. Earlee Products intended that polysorbate 20 would be added to solutions of antimicrobial agents as dips or sprays on processed raw products. Emulsifiers are food additives that facilitate the mixing of two liquids and the applicant claims that polysorbate 20 has superior emulsifying properties compared to other approved emulsifiers.

### COMMENTS

4. Polysorbate 20 has permissions in a number of other international and national jurisdictions including Codex Alimentarius, the EU, USA, Japan and Singapore. It has also been assessed by the FAO/WHO Joint Expert Committee on Food Additives (JECFA).
5. Polysorbates 20, 40, 60, 65 and 80 are chemically very similar, are metabolised by the same pathways and have similar adverse effects in laboratory animals, a group ADI is at a level as supported by JECFA, 0-25 mg/kg bodyweight/day, is appropriate. FSANZ undertook considerable work around the ADI but considered that it was unlikely that all foods within each permitted food category would contain polysorbates and unlikely that every consumer would select all of those foods to consume on a given day.
6. The safety assessment of the food additive identified that:
  - Polysorbate 20 was not pathogenic or toxigenic
  - the processing aid was not genotoxic
  - at a very high dose (25% w/w in the diet) polysorbate 20 causes diarrhoea and associated weight loss in laboratory rodents
  - there was no evidence to suggest that ‘no observed adverse effect level’ (NOAEL) for polysorbate 20 would be lower than for those of other polysorbates
  - the food additive does not present as a potential food allergen.
7. The FSANZ risk assessment concluded that there were no public health and safety issues associated with the use the applicant’s processing aid.
8. FSANZ also agreed that the use proposed was technologically justified at a maximum permitted level of 500 mg/kg. The applicants had sought use at GMP but the ADI was a

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'polysorbate food additive family' and that exposure to this family of food additives for high consumers of some of the sub-populations is close to the ADI.

9. Ensuring a wide variety of food additives are available to food manufacturers is vital to the continuing evolution, refinement and improvement of food processing.
10. NZFGC is therefore pleased to support the draft variation prepared by FSANZ that will permit the use of polysorbate 20 as a food additive.
11. NZFGC is not technically expert in the area of polysorbates so we are not clear on the relative effectiveness amongst polysorbates 20, 40, 65 and 80. We suggest, however, that at some time in the future, a review of selected 'food additive families' that have collective ADIs might be undertaken to ensure that the most efficient and effective substances in the family are not discriminated against simply because they were the last to be added to the Food Standards Code. We should be striving to provide that the most efficient and effective food additives are supported irrespective of when they were added to the Food Standards Code.