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[59-18]

Approval report – Application A1137

Polysorbate 20 as a Food Additive

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Earlee Products Pty Ltd to permit the use of polysorbate 20 as an emulsifier food additive for processed meat and meat products, and processed fish and fish products.

On 26 June 2018, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received four submissions.

FSANZ approved the draft variation on 5 September 2018. The Australia and New Zealand Ministerial Forum on Food Regulation was notified of FSANZ's decision on 18 September 2018.

This Report is provided pursuant to paragraph 33(1)(b) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

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Supporting document

The [following document](#)¹ which informed the assessment of this application is available on the FSANZ website:

SD1 Risk and technical assessment report

¹ <http://www.foodstandards.gov.au/code/applications/Pages/A1137.aspx>

Executive summary

Earlee Products Pty Ltd submitted an application in October 2016 to amend the *Australia New Zealand Food Standards Code* to permit the use of polyoxyethylene (20) sorbitan monolaurate, more commonly known as polysorbate 20, as a food additive.

The applicant sought permission to use polysorbate 20 as an emulsifier for use in processed meat products and processed fish and fish products. Emulsifiers are food additives that help two liquids to mix. Polysorbate 20 would be added to solutions of antimicrobial agents the applicant wishes to use as dips or sprays on processed raw and whole, comminuted meat, poultry, seafood and game products. Antimicrobial solutions extend the shelf-life of the treated food by inhibiting the growth of spoilage bacteria, and also pathogenic bacteria.

The applicant states that polysorbate 20 has superior emulsifying properties compared to other approved emulsifiers, including other polysorbates. Polysorbates, including polysorbate 20, have permissions in a number of national and international regulations, including Codex Alimentarius, the European Union, the United States of America, Japan and Singapore.

FSANZ determined that polysorbate 20 would perform the role stated in the application in the amounts and form proposed. Its use was therefore technologically justified and it has proven advantages over currently permitted emulsifiers.

All substances used as food additives must be listed in the statement of ingredients on most packaged foods.

Polysorbates are a group of chemically similar substances that includes three currently permitted food additives and polysorbate 20 (the food additive of this application). The hazard assessment confirmed that the group Acceptable Daily Intake (ADI) set by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and the US National Toxicology Program (NTP) was appropriate. This group ADI covers polysorbate 20.

A refined dietary exposure assessment was conducted that included the baseline of current polysorbate permissions and industry usage, and the additional exposure due to the requested permission for polysorbate 20. The dietary exposure did not exceed the ADI for any population groups, even at the 90th percentile.

No public health and safety issues were identified from FSANZ's assessment of permitting polysorbate 20 for the proposed purpose in addition to the currently permitted polysorbates.

The FSANZ Board has approved a draft variation to Schedules 8 and 15 of the Code to permit the use of polysorbate 20 as a food additive. This permission will be for the specific food groups proposed by the applicant being food categories 8.2, 8.3 and 9.2 in the table to section S15—5 and subject to a maximum permitted level of 500 mg/kg.

1 Introduction

1.1 The Applicant

The applicant was Earlee Products Pty Ltd, a manufacturer and supplier of ingredients and food premixes in Australia.

1.2 The Application

The purpose of the application was to seek permission for polyoxyethylene (20) sorbitan monolaurate (common name polysorbate 20) as a new emulsifier food additive.. Specifically the applicant proposes using polysorbate 20 in processed raw and whole, comminuted meat, poultry and game products (including but not exclusively goat, kangaroo, buffalo, emu, crocodile, wild boar and pheasant) and processed fish and fish products. The applicant intends to use the food additive to improve wetting properties of the surface of food treated with antimicrobial agents.

This food additive has the Codex Alimentarius International Numbering System (INS) assigned for food additives of number 432. Unless otherwise noted the common name of polysorbate 20 will be used throughout the report.

There are a number of similar substances which were considered part of the polysorbate group of food additives. This group of polysorbates were considered together for the purposes of risk assessment; i.e. the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and European Food Safety Authority (EFSA) established a group Acceptable Daily Intake (ADI) for the polysorbates. Section 2.1 of the Supporting Document 1 (SD1) lists the common names, chemical names and INS numbers of the five substances that make up the group of polysorbates. This table is not repeated here but the list is polysorbate 20, 40, 60, 65 and 80.

1.3 The current Standards

Australian and New Zealand food laws require food for sale to comply with the following Australia New Zealand Food Standards Code (the Code) requirements.

Permitted use

Paragraph 1.1.1—10(6)(a) of the Code provides that food for sale cannot contain, as an ingredient or component, a substance ‘used as a food additive’ unless that substance’s use as a food additive is expressly permitted by the Code.

Section 1.3.1—3 details which substances are permitted to be used as a food additive for the purposes of the Code. The permitted food additives for different food categories are listed in the table to section S15—5 of the Code.

Section 1.1.2—11 also provides that a substance is ‘used as a food additive’ if it is added to a food to perform one or more technological functions listed in Schedule 14 of the Code and is one of the following: a substance identified in the table to section S15—5 as permitted food additive; a substance identified in section 16—2 as an additive permitted at GMP; a substance identified in section 16—3 as an a colouring permitted at GMP; a substance identified in section 16—4 as an a colouring permitted at a maximum level; or a prescribed non-traditional food.

Schedule 14 lists the permitted technological purposes of food additives. The table in section

S14—2 of that Schedule provides that use as an emulsifier is a permitted purpose.

Schedules 15 and 16 list the specific food additive permissions for different categories of food products.

The Code currently permits the use of three polysorbate substances as food additives: polysorbate 80 (INS 433), polysorbate 60 (INS 435) and polysorbate 65 (INS 436). They are listed in the table to section S16—2 as food additives permitted at GMP (Good Manufacturing Practice) and so are permitted in a wide range of food categories as provided within the table to section S15—5.

Polysorbate 20 and polysorbate 40 are not currently permitted food additives in Australia and New Zealand.

Labelling

Paragraph 1.1.1—10(8) of the Code provides that food for sale must comply with all relevant labelling requirements imposed by the Code for that food.

Standard 1.2.4 of the Code generally requires food products to be labelled with a statement of ingredients. Subsection 1.2.4—7(1) of that Standard requires food additives to be declared in the statement of ingredients.

Schedule 8 (for statement of ingredients) lists the names and code numbers of food additives that are to be used for labelling purposes.

Schedule 8 does not refer to polysorbate 20 as this substance is not currently permitted to be added to food as a food additive.

Identity and purity requirements

Paragraph 1.1.1—15(1)(a) of the Code requires substances used as food additives to comply with any relevant identity and purity specifications listed in Schedule 3 of the Code. Schedule 3 provides specifications for polysorbate 20. See section 2.2.3 below.

1.3.1 International standards

The international and national permissions for the use of polysorbate 20 as a food additive that are relevant to this application are summarised below.

1.3.1.1 Codex Alimentarius

The Codex General Standard for Food Additives (CODEX STAN 192-1995, GSFA) contains a large number of provisions for the use of polysorbate 20 (within the provisions for polysorbates) within Table 1. The list of food categories and the maximum levels is not detailed here but can be located within the GSFA². Online searching of the GSFA is also available³.

² General Standard for Food Additives, CODEX STAN 192-1995, revision 2017 available http://www.fao.org/gsfaonline/docs/CXS_192e.pdf

³ GSFA online search available <http://www.fao.org/gsfaonline/additives/search.html?lang=en>

1.3.1.2 European Union

Similar to the GSFA, the European Union permits polysorbates (including polysorbate 20) in a wide variety of food categories. These permissions are contained in Annex II to Regulation (EC) No 1333/2008⁴. Food additive permissions can also be searched from an online website⁵. A summarised list of polysorbate permissions for food categories is also provided in Table 7 of the 2015 EFSA scientific opinion on the re-evaluation of polysorbates⁶.

1.3.1.3 United States of America

Polysorbate permissions for use as indirect food additives (adjuvants, production aids, and sanitizers) with the technological purpose as emulsifiers and/or surface-active agents in the United States is provided within the US Code of Federal Regulations (CFR)⁷ section 178.3400⁸. Polysorbates 60, 65 and 80 are also permitted in the CFR as food additives for direct addition to food for human consumption, but polysorbate 20 is not.

Polysorbate 20 is also permitted as a flavouring adjuvant⁹ due to section 172.515 (Synthetic flavoring substances and adjuvants) of the CFR¹⁰. Polysorbate 60 and 80 are also permitted flavouring adjuvants.

1.3.1.4 Other country permissions

Polysorbate 20 is permitted as a food additive in Japan¹¹ and Singapore¹².

1.4 Reasons for accepting Application

The application was accepted for assessment because:

⁴ COMMISSION REGULATION (EU) No 1129/2011 of 11 November 2011 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council by establishing a Union list of food additives, available <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L:2011:295:FULL&from=EN>

⁵

https://webgate.ec.europa.eu/foods_system/main/?event=substances.search&substances.pagination=1

⁶ EFSA ANS Panel (EFSA Panel on Food Additives and Nutrient Sources Added to Food), 2015. Scientific Opinion on the re-evaluation of polyoxyethylene sorbitan monolaurate (E 432), polyoxyethylene sorbitan monooleate (E 433), polyoxyethylene sorbitan monopalmitate (E 434), polyoxyethylene sorbitan monostearate (E 435) and polyoxyethylene sorbitan tristearate (E 436) as food additives. EFSA Journal 2015;13(7):4152, 74 pp

⁷ United States Food & Drug Administration, Code of Federal Regulation, section 178.3400, available <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/cfrsearch.cfm>

⁸ https://www.ecfr.gov/cgi-bin/text-idx?SID=ac79097fe6735334b83e5ce9757c5094&mc=true&node=pt21.3.178&rgn=div5#se21.3.178_13400

⁹ Flavouring adjuvant is a substance added to a flavouring preparation that aids in imparting the active flavouring substance to the food; in this case as an emulsifier.

¹⁰ United States Food & Drug Administration, Code of Federal Regulations, section 172.515, available <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm>

¹¹ Standards for Use of Food Additives, The Japan Food Chemical Research Foundation, available <http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/stanrd.use>

¹² Sixth Schedule (Permitted emulsifiers and permitted stabilisers), Regulation 21(2) – in Food Regulations, Agri-Food & Veterinary Authority of Singapore, available <https://www.ava.gov.sg/docs/default-source/legislation/sale-of-food-act/food-regulations38a28b1875296bf09fdaff00009b1e7c.pdf>

- it complied with the procedural requirements under subsection 22(2) of the FSANZ Act
- it related to a matter that warranted the variation of a food regulatory measure.

1.5 Procedure for assessment

The application was assessed under the General Procedure.

1.6 Decision

The draft variation as proposed following assessment was approved **without change**. The variation takes effect on gazettal. The approved draft variation is at Attachment A.

The related explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation.

2 Summary of the findings

2.1 Summary of issues raised in submissions

FSANZ sought public comments on the draft variation included in the Call for Submissions between 26 June 2018 and 24 July 2018.

Four submissions were received:

- 2 from government agencies (1 supportive and one did not explicitly state a position)
- 1 from an industry association (supportive)
- 1 from a consumer organisation (did not explicitly support or oppose though expressed concern about the safety of polysorbates and other emulsifiers).

The issues raised in submissions and FSANZ's responses are detailed in Table 1.

In summary the issues raised and FSANZ's responses were:

- A consumer organisation provided two references to support its view that polysorbates (and other emulsifiers) are not as benign as many believe. FSANZ assessed these references and concluded that they did not change the overall conclusion that polysorbate 20 (and the other three currently permitted polysorbates) is safe and suitable for the proposed purpose.
- Two issues raised in submissions were noted but these are outside the scope of the application and were not considered as part of the assessment.

Table 1: Summary of issues

Issue	Raised by	FSANZ response (including any amendments to drafting)
Two references were submitted suggesting this class of emulsifiers may not be safe.	Food Intolerance Network	FSANZ assessed the scientific merits of these two references and determined they do not change FSANZ’s overall conclusion that polysorbate 20 is both safe and suitable for the proposed purpose. It also does not change the assessment that the other three permitted polysorbate food additives are also safe.
Concern that emulsifiers disrupt microbiota and promote obesity, based on Chassaing et al (2015)	Food Intolerance Network	FSANZ previously reviewed Chassaing et al (2015). The paper reported that mice gained weight when administered 1% polysorbate 80 in drinking water, which is inconsistent with the results of other studies in mice, which tested much higher doses. Administration of polysorbates in the diet, at up to 7.5 g/kg bw/day, is consistently associated with weight loss in mice, rats and hamsters in numerous other studies (see review by EFSA, 2015). The toxicological significance of the Chassaing study is therefore unclear. The exposure levels in the Chassaing study significantly exceed likely human exposures of polysorbates. The level of emulsifier in the drinking water of the mice was approximately 1500 mg/kg bw/day. See a more detailed assessment in section 2.1.1 below.
Concern that emulsifiers are associated with gut leakage and autoimmune disease, based on Lerner and Matthias (2015)	Food Intolerance Network	FSANZ has reviewed Lerner and Matthias (2015). The paper mentions polysorbates only once and provides no evidence that they are associated with gut leakage or autoimmune diseases. FSANZ has not identified any evidence from other sources that dietary polysorbate exposure is associated with either gut leakage or autoimmune disease. See a more detailed assessment in section 2.1.2 below.

Issue	Raised by	FSANZ response (including any amendments to drafting)
<p>The preference would be for consideration of polysorbates as a group as this would more closely align the Code with the Codex GSFA, as this takes into account all the polysorbates that share a JECFA group ADI. It is understood this is outside the scope of the application and would be more appropriately dealt with under a wider review of permissions.</p>	<p>Ministry for Primary Industries (New Zealand)</p>	<p>The comment is noted as is the fact this is outside the scope of the application.</p>
<p>It is suggested that at some time in the future a review of selected 'food additive families' that have a collective ADI be undertaken. The justification for such work would be to ensure the most efficient and effective members of the families are not discriminated against just because they are the last added to the Code.</p>	<p>New Zealand Food & Grocery Council</p>	<p>The comment is noted but the request is outside the scope of the application.</p>

2.1.1 FSANZ's review of Chassaing et al (2015)

In this study, mice were exposed orally to either carboxymethylcellulose (CMC) or polysorbate 80 in drinking water or mouse chow at 1.0%. The authors reported that these treatments were associated with a number of changes including reduced thickness of the gut mucus, with greater proximity of gut bacteria to the gut epithelium, alterations in the composition of the gut microbe population, low-grade intestinal inflammation, impaired glycaemic control, and increases in food consumption, body weights and adipose deposition. It was also reported that 0.1% CMC in mouse chow resulted in increased bodyweight and blood glucose and 0.1% polysorbate 80 resulted in low-grade inflammation and increased adiposity. The authors concluded that additional studies would be required to establish the relevance of these findings to humans.

FSANZ does not consider these results are relevant to the assessment of polysorbates, for the following reasons:

- The increased bodyweights and adipose deposition observed in mice by Chassaing et al (2015) are inconsistent with the results of other studies of these emulsifiers in mice, which tested much higher doses. CMC at up to 10% of the diet had no effect on bodyweight in mice (Mondal and Yeasman 2016). In addition, administration of polysorbates in the diet of mice, at up to 7.5 g/kg bw/day, is consistently associated with weight loss in mice, rats and hamsters in numerous studies by other researchers (reviewed by the European Food Safety Authority (EFSA) (2015)).
- The exposure levels in the Chassaing et al study were very high and significantly exceed likely human exposures to CMC or polysorbate 80. For example, the level of emulsifier in the drinking water of the mice was approximately 1500 mg/kg bw/day, 0.1% emulsifier in the diet of a mouse is approximately 120 mg emulsifier/kg bw/day, and 1% emulsifier in the diet is 1200 mg/kg bw/day. In comparison, a recent dietary exposure assessment in the USA (Shah et al. 2017) found that the highest mean dietary exposure to CMC is approximately 30 mg/kg bw/day and that of polysorbate 80 is approximately 15 mg/kg bw/day. EFSA (2015) estimated that mean exposure to polysorbates in Europe ranges from 0.7 mg/kg bw/day in adults to 25 mg/kg bw/day in toddlers. The doses used in the mice are therefore far in excess of those seen in human populations.

References:

EFSA (2015). Scientific Opinion on the re-evaluation of polyoxyethylene sorbitan monolaurate (E 432), polyoxyethylene sorbitan monooleate (E 433), polyoxyethylene sorbitan monopalmitate (E 434), polyoxyethylene sorbitan monostearate (E 435) and polyoxyethylene sorbitan tristearate (E 436) as food additives. EFSA Journal 13(7): 4152, 74 pp. doi:10.2903/j.efsa.2015.4152

Mondal MI and Yeasmin MS (2016). Toxicity study of food-grade carboxymethyl cellulose synthesized from maize husk in Swiss albino mice. *Int J Biol Macromol.*92:965-971. doi: 10.1016/j.ijbiomac.2016.08.012.

Shah R, Kolanos R, DiNovi MJ, Mattia A and Kaneko KJ (2017). Dietary exposures for the safety assessment of seven emulsifiers commonly added to foods in the United States and implications for safety. *Food Additives & Contaminants. Part A* Apr 19, pp. 1-13. doi:10.1080/19440049.2017.1311420.

2.1.2 FSANZ's review of Lerner and Matthias (2015)

This review article presents the hypothesis that food additive consumption leads to autoimmune disease by increasing the permeability of tight junctions between intestinal epithelial cells. In Section 5.3 of the article, the authors discuss possible effects of emulsifiers on intestinal epithelial cell tight junctions. They cite *in vitro* studies, using Caco-2 cells, of disruption of tight junctions by sucrose monoester fatty acids; oleic and docosahexaenoic acids; fatty acids (EPA, DHA, γ LA, capric and lauric acids); sodium-cholate; Cremophor EL; Gelucire 44/14; sodium taurocholate; benzalkonium chloride and saponin. However no studies showing that polysorbates disrupt tight junctions were cited by the authors, or located by FSANZ by literature search. FSANZ notes that some of the substances named, such as fatty acids and saponins, are normal components of the diet of humans and closely related primates, while the body itself synthesizes cholic acid and excretes it into the intestinal lumen as part of bile. Thus, the significance of results from an *in vitro* assay of transformed cells to normal intestinal function *in vivo* is unclear. Overall this review article fails to present any new *in vivo* evidence of adverse effects of emulsifiers, and specifically polysorbates in the diet.

2.2 Risk assessment

FSANZ conducted a risk assessment of polysorbate 20 as a food additive for use on processed meat products, and processed fish and fish products, (refer SD1). The conclusions of this assessment are provided below.

Polysorbate 20 is technologically justified for its proposed stated purpose as an emulsifier to surface treat processed meat products, and fish and fish products. The assessment concluded it is able to perform this function in the amounts and form proposed to be used, and it has proven advantages over other emulsifiers. There are internationally accepted specifications and analytical methods available to confirm the levels of polysorbate 20 in treated food.

The submitted data, and information from other sources, are considered adequate to define the hazard of polysorbate 20. The available evidence shows that polysorbate 20 is not genotoxic. At the very high dose of 25% w/w in the diet, polysorbate 20 causes diarrhoea and associated weight loss and ill-health in laboratory rodents. However, these adverse effects would not be observed in humans since these levels are extremely high and not relevant to human consumption levels. There is no evidence that polysorbates are reproductive or developmental toxicants. Although clinical data on human tolerance are limited, polysorbates are widely used as emulsifiers in foods and pharmaceuticals internationally, and have not been associated with adverse effects in consumers. Polysorbates 60, 65 and 80 are already permitted in the Australia New Zealand Food Standards Code (the Code) at levels consistent with Good Manufacturing Practice (GMP).

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. The group ADI established by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 1973 was based on chronic dietary studies of polysorbates 60, 65 and 80 in rats. A no observed adverse effect level (NOAEL) of 5% in the diet (equivalent to 2500 mg/kg bodyweight (bw)/day) was based on the occurrence of diarrhoea and associated weight loss and ill-health at the next highest dose of 10% (5000 mg/kg bw/day). From this NOAEL, JECFA established a group ADI for dietary polysorbates of 0-25 mg/kg bw/day. Results of a chronic dietary study of polysorbate 80 in rats, conducted by the National Toxicology Program (NTP) in 1992, confirmed the JECFA ADI, and FSANZ has found no evidence to suggest that the NOAEL for polysorbate 20 would be expected to be lower than those of the other polysorbates.

Given that the group ADI is intended to cover dietary exposure to all polysorbates, FSANZ

undertook a dietary exposure assessment for polysorbate 20 plus all other permitted polysorbates. FSANZ completed a refined estimate of dietary exposure to polysorbates based on current Australian and New Zealand industry use levels, as well as a scenario that included the additional proposed uses for polysorbates 20. The estimated refined baseline mean and 90th percentile exposure to polysorbates expressed on a kilogram body weight basis ranged from 4.8–10.4 mg/kg bw/day and 10.7–23.7 mg/kg bw/day, respectively across all Australian and New Zealand population groups assessed. When meat and fish products containing polysorbate 20 at the amount requested by the applicant were included, the estimated total mean and 90th percentile dietary exposures to polysorbates ranged from 5.0–10.8 mg/kg bw/day and 11.2–24.7 mg/kg bw/day, respectively. The estimated chronic dietary exposure is a conservative overestimate as it is unlikely that all foods within each permitted food category would contain polysorbates. In addition, it is unlikely that consumers will select all foods containing polysorbates on a given day.

Based on the review of the toxicological data, including consideration of reviews by other regulatory agencies, FSANZ concludes that it is appropriate to include polysorbate 20 in a group ADI for polysorbates, and that the group ADI established by JECFA in 1973 for polysorbates, 0-25 mg/kg bw/day, remains appropriate. The mean and 90th percentile refined baseline exposure estimates of polysorbates already permitted in the Code were below the ADI of 25 mg/kg bw/day for all Australian and New Zealand population groups assessed. When the additional requested permissions of polysorbate 20 was applied, the mean and 90th percentile exposures for all population groups assessed did not exceed the ADI.

Based on dietary exposure assessment, the group ADI will not be exceeded by the addition of polysorbate 20 to the proposed food categories requested in addition to the permitted polysorbates in the Code.

On the basis of these considerations, the risk assessment concluded that there are no public health and safety concerns with permitting polysorbate 20 as an emulsifier food additive for processed meat and meat products, and processed fish and fish products.

2.3 Risk management

On the basis of the results of FSANZ's risk assessment, it is appropriate to accept the applicant's request to permit polysorbate 20 as a food additive emulsifier in processed meat and meat products, and processed fish and fish products.

2.3.1 Permissions for processed meat and processed fish products

The application sought permission to use polysorbate 20 as a food additive in specific categories of food products listed in the table to section S15—5. These are summarised in Table 1. The requested Maximum Permitted Level (MPL) for each category is 500 mg/kg. However the applicant requested the food additive be permitted to be used at GMP comparable to permissions for polysorbate 60, 65 and 80 and, for that reason, asked that the substance be listed in section S16—2 as an additive permitted at GMP.

Table 1: Food categories for which applicant is seeking permission for polysorbate 20, including Maximum Permitted Level (MPL)

Food category	Food category description	MPL mg/kg
8.2	Processed meat, poultry and game products in whole cuts or pieces	500
8.3	Processed comminuted meat, poultry and game products	500
9.2	Processed fish and fish products	500

FSANZ's Food Technology assessment (sections 2.1.3 and 2.1.4 of SD1) confirmed the claimed benefit of the application that polysorbate 20 used as an emulsifier in the amounts and form proposed in conjunction with various plant based extracts containing active antimicrobials provides antimicrobial activity and concomitant shelf-life improvement. It is therefore appropriate to permit polysorbate 20 as a food additive for the food categories 8.2, 8.3 and 9.2 with the MPL at 500 mg/kg in the table to section S15—5. It is not appropriate to add polysorbate 20 as a GMP food additive to the tables to section S16—2 since an ADI has been established for the polysorbate food additive family and the dietary exposure assessment has indicated that exposure to the food additives for high consumers of some sub-populations is close to the ADI.

2.3.2 Labelling considerations

Section 1.2.4—7 in Standard 1.2.4 requires substances used as food additives to be declared in the statement of ingredients on the label of most packaged foods. This can occur in either of two ways:

- If the substance can be classified into a class of additives listed in Schedule 7 then:
 - the class name is to be declared (e.g. 'emulsifier') as indicated in Schedule 7,
 - followed in brackets by the name or code number of the substance as indicated in Schedule 8 – Food additive names and code numbers (for statement of ingredients).
- Otherwise, the name of the substance as indicated in Schedule 8 is to be declared.

These labelling provisions will apply to the use of polysorbate 20 in processed meat products and processed fish and fish products, allowing consumers to identify whether this food additive is present in the food.

There are some exemptions to the above requirements for foods for sale that are not required to bear a label. These exemptions are set out in section 1.2.1—6 in Standard 1.2.1, and include a food that is made and packaged on the premises from which it is sold, or is packaged in the presence of the purchaser, or is delivered packaged, and ready for consumption, at the express order of the purchaser.

All of the above labelling requirements and exemptions apply in the same manner to the use of polysorbates 60, 65 and 80.

2.3.3 Specifications

Paragraph 1.1.1—15(1)(a) of Standard 1.1.1 requires that permitted food additives comply with a relevant specification listed in Schedule 30. As noted in section 2.4.1 of SD1, there are international specifications for the group polysorbate food additives (which includes polysorbate 20). These specifications are primary sources within section S3—2. These primary sources of specifications are JECFA (paragraph S3—2(1)(b)), Food Chemicals Codex (paragraph S3—2(1)(c)) and the European Commission (paragraph S3—2(1)(d)).

2.3.4 Analytical methods

Section 2.3 of SD1 notes there are a number of suitable analytical methods for the detection and quantification of polysorbates in food.

2.4 Risk communication

2.4.1 Consultation

Consultation is a key part of FSANZ's standards development process. FSANZ acknowledges the time taken by individuals and organisations to make submissions on this application. Every submission was considered by the FSANZ Board. All comments are valued and contribute to the rigour of our assessment.

FSANZ developed and applied a basic communication strategy to this Application. The call for submissions was notified via the Food Standards Notification Circular, media release, FSANZ's social media tools and Food Standards News.

The process by which FSANZ considers standard development matters is open, accountable, consultative and transparent.

The Applicant, individuals and organisations that made submissions on this application will be notified at each stage of the assessment.

2.5 FSANZ Act assessment requirements

2.5.1 Section 29

2.5.1.1 Consideration of costs and benefits

The Office of Best Practice Regulation, in a letter dated 24 November 2010 (reference 12065), provided a standing exemption from the need to assess if a Regulation Impact Statement is required for applications relating to food additives, as they are machinery in nature and their use is voluntary.

However, notwithstanding that exemption, the FSANZ Act requires FSANZ to have regard to whether costs that would arise from the proposed measure outweigh the direct and indirect benefits to the community, government or industry that would arise from the proposed measure (S.29 (2)(a)). The purpose of this consideration is to determine if the community, government, and industry as a whole is likely to benefit, on balance, from a move from the status quo. Approving the application is the only proposed measure that has been considered against the status quo (i.e. rejecting the application).

The consideration of the costs and benefits in this section was not intended to be an exhaustive, quantitative economic analysis of the proposed measures. Rather, the consideration sought to highlight the likely positives and negatives of moving away from the status quo by approving the application.

FSANZ is required to consider the impact of various regulatory and non-regulatory options on all sectors of the community, especially relevant stakeholders who may be affected by this application. The level of analysis was commensurate with the nature of the application and significance of the impacts.

FSANZ's assessment was that the direct and indirect benefits that would arise from a food regulatory measure developed or varied as a result of the application outweighed the costs to the community, government or industry that would arise from developing or varying that food regulatory measure. The reason for this conclusion is that approving permission for polysorbate 20 as an emulsifier for processed meat and meat products, and processed fish and fish products provides benefits to the food industry, without any costs to governments and consumers. Polysorbate 20 has better emulsifying properties for certain types of

processes compared to currently permitted emulsifiers. This includes better wetting properties of the meat and fish surfaces to be treated with antimicrobial agents to reduce microbial load on these products.

2.5.1.2 Other measures

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure developed or varied as a result of the application.

2.5.1.3 Any relevant New Zealand standards

Standards 1.1.1, 1.1.2, 1.2.4 and 1.3.1 and Schedules 7, 8, 14, 15 and 16 apply in both Australia and New Zealand. There are no relevant New Zealand only Standards.

2.5.1.4 Any other relevant matters

Other relevant matters are considered below.

2.5.2 Subsection 18(1)

FSANZ has also considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

2.5.2.1 Protection of public health and safety

FSANZ undertook a safety assessment (SD1) and concluded there are no public health and safety concerns with permitting the use of polysorbate 20 in the production of processed meat products and processed fish and fish products.

2.5.2.2 The provision of adequate information relating to food to enable consumers to make informed choices

The labelling requirements for polysorbate 20 as a food additive are discussed in section 2.3.2 – Labelling considerations. These requirements provide information to enable consumers to make informed choices.

2.5.2.3 The prevention of misleading or deceptive conduct

There are no issues identified with this application relevant to this objective.

2.5.3 Subsection 18(2) considerations

FSANZ has also had regard to:

- **the need for standards to be based on risk analysis using the best available scientific evidence**

FSANZ used the best available scientific evidence to conduct the risk analysis, which is provided in SD1. The applicant submitted a dossier of scientific studies as part of its application. Other technical information, including scientific literature, was also used in assessing the application.

- **the promotion of consistency between domestic and international food standards**

Polysorbate 20 is permitted as a food additive in a number country's food regulations, as well

as in the Codex GSFA, as part of the group of polysorbate food additives (see section 1.3.1). Permitting the use of polysorbate 20 will promote consistency of food regulations between Australia and New Zealand and international standards.

- **the desirability of an efficient and internationally competitive food industry**

Permission to use polysorbate 20 in the production of processed meat and meat products, and processed fish and fish products will provide improved efficiencies for Australian and New Zealand producers as polysorbate 20 has advantages over other polysorbates and emulsifiers. In particular, this is to improve wetting properties of the surface of food treated with antimicrobial agents.

- **the promotion of fair trading in food**

No issues were identified for this application relevant to this objective.

- **any written policy guidelines formulated by the Forum on Food Regulation**

The [Policy Guideline for the Addition to Food of Substances other than Vitamins and Minerals](#)¹³ includes specific order policy principles for substances added to achieve a solely technological function, such as food additives. These specific order policy principles state that permission should be granted where:

- the purpose for adding the substance can be articulated clearly by the manufacturer as achieving a solely technological function (i.e. the 'stated purpose')
- the addition of the substance to food is safe for human consumption
- the amounts added are consistent with achieving the technological function
- the substance is added in a quantity and a form which is consistent with delivering the stated purpose
- no nutrition, health or related claims are to be made in regard to the substance.

FSANZ determined that permitting the use of polysorbate 20 as an emulsifier food additive for treating processed meat and meat products, and processed fish and fish products is consistent with the specific order principles.

Attachments

- A. Approved draft variation to the *Australia New Zealand Food Standards Code*
- B. Explanatory Statement

¹³ <http://foodregulation.gov.au/internet/fr/publishing.nsf/Content/publication-Policy-Guideline-on-the-Addition-of-Substances-other-than-Vitamins-and-Minerals>

Attachment A – Approved draft variation to the *Australia New Zealand Food Standards Code*



Food Standards (Application A1137 – Polysorbate 20 as a Food Additive) Variation

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The variation commences on the date specified in clause 3 of the variation.

Dated [To be completed by Standards Management Officer]

Standards Management Officer
Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC **XX on XX Month 20XX**. This means that this date is the gazettal date for the purposes of the above notice.

1 Name

This instrument is the *Food Standards (Application A1137 – Polysorbate 20 as a Food Additive) Variation*.

2 Variation to a Standard in the Australia New Zealand Food Standards Code

The Schedule varies a standard in the *Australia New Zealand Food Standards Code*.

3 Commencement

The variation commences on the date of gazettal.

Schedule

[1] Schedule 8 is varied by

[1.1] omitting the following from the table to section S8—2,

Polyoxyethylene (40) stearate	431
-------------------------------	-----

substituting

Polyoxyethylene (40) stearate	431
-------------------------------	-----

Polysorbate 20 or Polyoxyethylene (20) sorbitan monolaurate	432
---	-----

[1.2] omitting the following from the table to section S8—2,

431	Polyoxyethylene (40) stearate
-----	-------------------------------

substituting

431	Polyoxyethylene (40) stearate
-----	-------------------------------

432	Polysorbate 20 or Polyoxyethylene (20) sorbitan monolaurate
-----	---

[2] Schedule 15 is varied by

[2.1] omitting the following from item 8.2 of the table to section S15—5,

280 281 282 283	Propionic acid and sodium and potassium and calcium propionates	GMP
-----------------	---	-----

substituting

280 281 282 283	Propionic acid and sodium and potassium and calcium propionates	GMP
-----------------	---	-----

432	Polyoxyethylene (20) sorbitan monolaurate	500
-----	---	-----

[2.2] omitting the following from item 8.3 of the table to section S15—5,

280 281 282 283	Propionic acid and sodium and potassium and calcium propionates	GMP
-----------------	---	-----

substituting

280 281 282 283	Propionic acid and sodium and potassium and calcium propionates	GMP
432	Polyoxyethylene (20) sorbitan monolaurate	500

[2.3] omitting the following from item 9.2 of the table to section S15—5,

Colourings permitted to a maximum level

substituting

	Colourings permitted to a maximum level	
432	Polyoxyethylene (20) sorbitan monolaurate	500

Attachment B – Explanatory Statement

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 1 of Part 3 of the FSANZ Act specifies that the Authority may accept applications for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering an application for the development or variation of food regulatory measures.

FSANZ accepted application A1137 which sought to use polysorbate 20 as an emulsifier for processed meat and meat products, and processed fish and fish products. The Authority considered the application in accordance with Division 1 of Part 3 and has prepared a draft variation.

Following consideration by the Australia and New Zealand Ministerial Forum on Food Regulation, section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

Section 94 of the FSANZ Act specifies that a standard, or a variation of a standard, in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sunseting under the *Legislation Act 2003*.

2. Purpose

The Authority has approved the draft variation to amend the table to section S15—5 to permit the use of polysorbate 20 as a food additive on processed meat and meat products and on processed fish and fish products. The draft variation also amends the alphabetical and numerical listings in the table to section S8—2 to provide a name and code number for polysorbate 20 to be used for labelling purposes.

3. Documents incorporated by reference

The variations to food regulatory measures do not incorporate any documents by reference.

4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of application A1137 included one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary. Submissions were called for on 26 June 2018 for a four-week consultation period.

A Regulation Impact Statement was not required because the proposed variations to Schedule 15 are likely to have a minor impact on business and individuals.

5. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the FSANZ Act.

6. Variation

Item [1.1]

Item [1.1] of the draft variation amends the alphabetical listing in the table to section S8—2 by inserting the food additive name 'Polysorbate 20 or Polyoxyethylene (20) sorbitan monolaurate' and code number '432' into that listing in alphabetical order.

Item [1.2]

Item [1.2] amends the numerical listing in the table to section S8—2 by inserting the food additive code number '432' and name 'Polysorbate 20 or Polyoxyethylene (20) sorbitan monolaurate' into that listing in numerical order.

Item [2.1]

Item [2.1] amends item 8.2 of the table to section S15—5. Item 8.2 relates to processed meat, poultry and game products in whole cuts or pieces. The amendment inserts into item 8.2 a reference to polyoxyethylene (20) sorbitan monolaurate (INS number 432), with a maximum permitted level of 500 mg/kg. The effect of the amendment is to permit that substance's use as a food additive within that category of food products subject to that maximum permitted level.

Item [2.2]

Item [2.2] amends item 8.3 of the table to section S15—5. Item 8.3 relates to processed comminuted meat, poultry and game products, other than products listed in item 8.3.2. The amendment inserts into item 8.3 a reference to polyoxyethylene (20) sorbitan monolaurate (INS number 432), with a maximum permitted level of 500 mg/kg. The effect of the amendment is to permit that substance's use as a food additive in that category of food products subject to that maximum permitted level.

Item [2.3]

Item [2.3] amends item 9.2 of the table to section S15—5. Item 9.2 relates to processed fish and fish products. The amendment inserts into item 9.2 a reference to polyoxyethylene (20) sorbitan monolaurate (INS number 432), with a maximum permitted level of 500 mg/kg. The effect of the amendment is to permit that substance's use as a food additive in that category of food products subject to that maximum permitted level.