

26 June 2018
[51–18]

Call for submissions – Application A1137

Polysorbate 20 as a Food Additive

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, and has prepared a draft food regulatory measure. Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

For information about making a submission, visit the FSANZ website at [information for submitters](#).

All submissions on applications and proposals will be published on our website. We will not publish material that that we accept as confidential, but will record that such information is held. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1991*. Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available on CD, rather than on the website.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at [information for submitters](#).

Submissions should be made in writing; be marked clearly with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website via the link on [documents for public comment](#). You can also email your submission directly to submissions@foodstandards.gov.au.

There is no need to send a hard copy of your submission if you have submitted it by email or via the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 24 July 2018

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions about making submissions or the application process can be sent to standards.management@foodstandards.gov.au.

Hard copy submissions may be sent to one of the following addresses:

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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 is seeking 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 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 is therefore technologically justified and it has proven advantages over currently permitted emulsifiers.

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 a very high dose of 25% w/w in the diet, polysorbate 20 causes diarrhoea and associated weight loss and ill-health in laboratory rodents. There is no evidence that the polysorbates are reproductive or developmental toxicants.

Because 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 Acceptable Daily Intake (ADI) is appropriate. FSANZ agrees with the determination of the group ADI of 0-25 mg/kg bodyweight/day established by the Joint FAO/WHO Expert Committee on Food Additives (JECFA).

A refined dietary exposure assessment for polysorbates was conducted based on the most recent Australian and New Zealand consumption data and information on reported use levels by industry and/or Codex GSFA or EU maximum permitted levels. When the additional requested permissions of polysorbate 20 were applied, the mean and 90th percentile exposures for all Australian and New Zealand population groups assessed did not exceed the ADI (25 mg/kg bw/day).

The refined estimated baseline exposures is conservative and is not considered to reflect actual dietary exposures. This is because it is unlikely that all foods in each permitted food category would contain polysorbates at maximum concentrations and unlikely that every consumer would select all of the foods that they consume to be foods containing polysorbates every day for a lifetime. Therefore, 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.

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

1 Introduction

1.1 The Applicant

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

1.2 The Application

The purpose of the application is to seek permission for polyoxyethylene (20) sorbitan monolaurate (common name polysorbate 20) as a new emulsifier food additive, for use in processed meat products and processed fish and fish products. 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 ensure improved surface wetting properties of the surfaces to be treated with antimicrobial agents to reduce microbial load on the products.

The food additive has the Codex Alimentarius International Numbering System (INS) 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 are considered part of the polysorbate group of food additives. This group of polysorbates are 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) derived a group Acceptable Daily Intake (ADI) for the polysorbates. Section 2.1 of the Supporting Document 1 (SD1) lists the common names, detailed 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 S16—2 as an additive permitted at GMP (Good Manufacturing Practice); a substance identified in section S16—3 as an a colouring permitted at GMP; a substance identified in section S16—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 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 to be added to food as a food additive.

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.

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 long 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.

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

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>

⁴ COMMISSION REGULATION (EU) No 1129/2011 of 11 November 2011 amending Annex II to

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:

- 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 is being assessed under the General Procedure.

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

[idx?SID=ac79097fe6735334b83e5ce9757c5094&mc=true&node=pt21.3.178&rqn=div5#se21.3.178_13400](https://www.ecfr.gov/cgi-bin/text-idx?SID=ac79097fe6735334b83e5ce9757c5094&mc=true&node=pt21.3.178&rqn=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/standrd.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-regulations38a28b1875296bf09daff00009b1e7c.pdf>

2 Summary of the assessment

2.1 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 concludes it is able to perform this function in the amounts and form proposed to be used, and it has proven advantages over other forms of emulsifiers. There are internationally accepted specifications and analytical methods available to check and quantify 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 the 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 set 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 derived a group ADI for dietary polysorbates in human beings 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, support 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 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 dietary exposure is conservative and considered to be an overestimate of chronic dietary exposure as it would be unlikely that all foods within each permitted food category would contain polysorbates and unlikely that every consumer will select all of the foods that they consume to be the ones 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, it is anticipated that this 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 relating to permitting polysorbate 20 as an emulsifier food additive for processed meat and meat products, and processed fish and fish products.

2.2 Risk management

It is understood that the dietary exposure assessment has very conservative assumptions in it, as explained and highlighted in section 4.2.3 of SD1. This is important because for some sub-population (New Zealand children aged 2-5 years) the 90th percentile dietary exposure for all polysorbates and additional exposure due to polysorbate 20 is close to or equal to 100% of the ADI. 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.

2.2.1 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.

2.2.2 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 the following two ways:

- If the substance can be classified into a class of additives listed in Schedule 7 — Food additive class names (for statement of ingredients), then:
 - the class name 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 and 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.

2.2.3 Specifications

Section 1.1.1—15 requires that permitted food additives (paragraph 1.1.1—15(1)(a)) need to comply with a specification within Schedule 3 – Identity and Purity. 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)).

2.2.4 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.

2.3 Risk communication

2.3.1 Consultation

Consultation is a key part of FSANZ's standards development process. FSANZ developed and applied a basic communication strategy to this application. All calls for submissions are 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. Public submissions are called to obtain the views of interested parties on issues raised by the application and the impacts of regulatory options.

The draft variation will be considered for approval by the FSANZ Board taking into account public comments received from this call for submissions.

2.3.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO members where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

There are relevant international standards and amending the Code to permit polysorbate 20 as an emulsifier food additive is unlikely to have a significant effect on international trade as the substance is permitted as a food additive in many food categories in the Codex Alimentarius General Standard for Food Additives and in many country's food regulations. Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Application of Sanitary and Phytosanitary Measures Agreement was not considered necessary.

2.4 FSANZ Act assessment requirements

When assessing this application and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters as required by section 29 of the FSANZ Act:

2.4.1 Section 29

2.4.1.1 Consideration of costs and benefits

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 benefits and costs associated with the proposed amendments to the Code were analysed using regulatory impact principles. The level of analysis was commensurate with the nature of the application and significance of the impacts.

Two regulatory options were considered:

1. prepare a draft variation to permit the food additive, polysorbate 20
2. reject the application.

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, FSANZ undertook a limited impact analysis.

A consideration of the costs and benefits of the regulatory options was not intended to be an exhaustive, quantitative economic analysis of the options and, in fact, most of the effects that were considered cannot be assigned a dollar value.

Rather, the assessment sought to highlight the qualitative effects of criteria that were relevant to each option. These criteria are deliberately limited to those involving broad areas such as trade, consumer information and compliance.

Option 1 – Prepare a draft variation

Sector	Costs or benefits to sector
Consumers	There are no direct costs or benefits to consumers associated with this option.
Industry	There are benefits to certain food businesses and processes from using this emulsifier over those of currently permitted emulsifiers. See, for example, section 2.4.3 below.
Governments	There are no direct costs or benefits to governments associated with this option.

Option 2 – Reject the Application

Sector	Costs or benefits to sector
Consumers	There are no direct benefits or costs to consumers of this option.
Industry	There are no benefits but some costs to industry from this option, as an alternative emulsifier which has claimed advantages over the currently permitted emulsifiers for certain purposes will not be available.
Governments	There are no benefits or costs to governments for this option.

The direct and indirect benefits that would arise from a food regulatory measure developed or varied as a result of the application outweigh the costs to the community, Government or industry that would arise from the development or variation of the food regulatory measure.

2.4.1.2 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.

2.4.1.3 Any relevant New Zealand standards

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

2.4.1.4 Any other relevant matters

Other relevant matters are considered below.

2.4.2 Subsection 18(1)

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

2.4.2.1 Protection of public health and safety

FSANZ has undertaken 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 and meat products, and processed fish and fish products.

2.4.2.2 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 2.2.2 – Labelling considerations. These requirements provide information to enable consumers to make informed choices.

2.4.2.3 The prevention of misleading or deceptive conduct

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

2.4.3 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 has 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 their 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 for the proposed purpose 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 ensure improved surface wetting properties of the surfaces to be treated with antimicrobial agents to reduce microbial load on the products.

- **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

¹³ <http://www.foodstandards.gov.au/code/fofr/fofrpolicy/pages/default.aspx>

- 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 has 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.

3 Draft variation

The draft variation to the Code is at Attachment A and is intended to take effect on gazettal.

A draft 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.

Attachments

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

Attachment A – 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

Glen Neal
General Manager, Risk Management & Intelligence
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 Standards in the Australia New Zealand Food Standards Code

The Schedule varies standards 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

432	Colourings permitted to a maximum level Polyoxyethylene (20) sorbitan monolaurate	500
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Attachment B – Draft 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 seeks to the use of 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.

2. Purpose

The purpose of the draft variation is 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 will include one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary. A call for submissions (including draft variations) will occur for a six-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 meat, poultry and game products in whole cuts or pieces. 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.