

3 September 2020
[134–20]

Call for submissions – Application A1191

Mono- and diglycerides of fatty acids (INS 471) as glazing agent for fruits and vegetables

FSANZ has assessed an application made by Apeel Sciences to extend the use of the food additive mono- and diglycerides of fatty acids (INS 471) as a glazing agent for fresh fruits and vegetables 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 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 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) 15 October 2020

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:

Food Standards Australia New Zealand
PO Box 5423
KINGSTON ACT 2604
AUSTRALIA
Tel +61 2 6271 2222

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6143
NEW ZEALAND
Tel +64 4 978 5630

Table of contents

EXECUTIVE SUMMARY	2
1 INTRODUCTION.....	3
1.1 THE APPLICANT.....	3
1.2 THE APPLICATION	3
1.3 THE CURRENT STANDARD	3
1.3.1 <i>Australia and New Zealand standards</i>	3
1.3.2 <i>International standards</i>	4
1.4 REASONS FOR ACCEPTING APPLICATION	5
1.5 PROCEDURE FOR ASSESSMENT	5
2 SUMMARY OF THE ASSESSMENT.....	5
2.1 RISK ASSESSMENT	5
2.2 RISK MANAGEMENT	6
2.2.1 <i>Labelling considerations</i>	6
2.2.2 <i>Risk management conclusion</i>	7
2.3 RISK COMMUNICATION.....	7
2.3.1 <i>Consultation</i>	7
2.3.2 <i>World Trade Organization (WTO)</i>	7
2.4 FSANZ ACT ASSESSMENT REQUIREMENTS	8
2.4.1 <i>Section 29</i>	8
2.4.2 <i>Subsection 18(1)</i>	9
2.4.3 <i>Subsection 18(2) considerations</i>	10
3 DRAFT VARIATION	11
4 REFERENCES.....	11
ATTACHMENT A – DRAFT VARIATION TO THE AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE.....	12
ATTACHMENT B – DRAFT EXPLANATORY STATEMENT.....	14

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 <https://www.foodstandards.gov.au/code/applications/Pages/A1191.aspx>

Executive summary

An application was received from Apeel Sciences seeking to extend the use of the currently permitted food additive, mono- and diglycerides of fatty acids (with the food additive International Numbering System (INS) of 471) as a glazing agent for fresh fruits and vegetables in the Australia New Zealand Food Standards Code (the Code). The purpose of applying the food additives as a glazing agent is to extend the shelf life of the treated fruits and vegetables and so reduce wastage through the supply chain. Mono- and diglycerides of fatty acids is a permitted food additive used at Good Manufacturing Practice (GMP) but it does not have permission for the proposed purpose of use as a glazing agent for fresh fruit and vegetables.

The food additive is specifically permitted for use as a glazing agent for fruits and vegetables in a number of countries including; Chile, China, the European Union (certain fruits, but not vegetables), Japan, Mexico, Peru and the United States. There are also provisions for its use as a glazing agent to treat fresh fruits and vegetables at GMP in the Codex Alimentarius General Standard for Food Additives.

An assessment of data provided by the applicant has concluded that the food additive mono- and diglycerides of fatty acids performs the technological purpose of a glazing agent to extend the shelf life of various treated fresh fruits and vegetables. A comparison of results indicate mono- and diglycerides of fatty acids performs better than untreated product, and conventional waxes and resins. As an already permitted GMP food additive, it complies with internationally accepted specifications of identity and purity, which are primary sources of specifications in Schedule 3 of the Code.

FSANZ concludes that the composition of the food additive mono- and diglycerides of fatty acids does not differ significantly from dietary lipids and a numerical ADI is not required. Estimated mean dietary exposure for Australian and New Zealand populations to mono- and diglycerides of fatty acids if used as a glazing agent on surface treated fruits and vegetables represents 0.6-0.8% of mean total fat intake, which is within normal daily variation.

The usual labelling requirements for food additives apply for the extension of use of mono- and diglycerides of fatty acids as a glazing agent for fresh fruits and vegetables as detailed within subsection 1.2.4—7(1). There are exemptions for labelling that applies for whole or cut fresh fruit or vegetables in a package that does not obscure the nature or quality of the food.

From the risk assessment and risk management conclusions it is proposed to permit the extension of use of the food additive mono- and diglycerides of fatty acids (INS 471) to treat fresh fruits and vegetables by adding the permission to the food sub subclass 4.1.2 (Surface treated fruits and vegetables) in the table to section S15—5, with the maximum permitted level of GMP.

1 Introduction

1.1 The applicant

Apeel Sciences develops and manufactures products to extend the shelf life and postharvest quality of fresh produce (essentially fresh fruits and vegetables).

1.2 The application

The application seeks to extend the use of the currently permitted food additive used at Good Manufacturing Practice (GMP) (GMP food additive), mono- and diglycerides of fatty acids (with the food additive International Numbering System (INS) of 471) as a glazing agent for fresh fruits and vegetables. The purpose of applying the food additives as a glazing agent is to extend the shelf life of the treated fruits and vegetables and so reduce wastage through the supply chain.

1.3 The current standard

1.3.1 Australia and New Zealand standards

Australian and New Zealand food laws require food for sale to comply with the following requirements of the Code, as relevant to this application.

1.3.1.1 *Food additives*

Paragraph 1.1.1—10(6)(a) provides that, unless expressly permitted by the Code, a food for sale must not have, as an ingredient or component, a substance that is used as a food additive.

Section 1.1.2—11 defines the expression 'used as a food additive'. Subsection 1.1.2—11(1) provides that a substance is 'used as a food additive' in relation to a food if both of the following conditions are met: the substance is added to the food to perform one or more technological functions listed in Schedule 14; and the substance is identified in subsection 1.1.2—11(2) – this includes a substance identified in the table to section S15—5 as a permitted food additive or a permitted substance (food additive) listed in sections S16—2, S16—3 or S16—4 of the Code.

Section 1.3.1—3 details when substances are permitted to be used as food additives in food.

Schedule 14 lists the permitted technological purposes of food additives. The table in section S14—2 provides that use as a glazing agent is a permitted purpose.

Schedule 15 lists the specific food additive permissions for different categories of foods in the table to section S15—5. The relevant food category for this application is 4.1.2 – Surface treated fruits and vegetables, under the subcategory 4.1 – Unprocessed fruits and vegetables. There is no permission for the food additive mono- and diglycerides of fatty acids for this food category.

Schedule 16 sets out the types of substances that may be used as food additives in any food at Good Manufacturing Practice (GMP) levels. Mono- and diglycerides of fatty acids is listed in the tables within section 16—2 so it is a GMP food additive. Such GMP food additives are permitted to be added to many different types of food categories due to listings within the table to section S15—5, however not the relevant food category for this application, 4.1.2.

1.3.1.2 Identity and purity requirements

Paragraph 1.1.1—15(1)(a) require substances used as food additives to comply with any relevant identity and purity specifications listed in Schedule 3.

Primary sources of relevant specifications are listed in section S3—2, being the Combined Compendium of JECFA food additive specifications (JECFA 2017) (para S3—2(1)(b)), Food Chemicals Codex (United States Pharmacopeia 2018) (para S3—2(1)(c) and the EU Commission Regulation No 231/2012 (EU Commission Regulation 2012) (para S3—1(b)(d)).

1.3.1.3 Labelling requirements

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

The Code's labelling requirements which apply to foods for retail sale and to foods sold to a caterer are set out in Divisions 2 and 3 of Standard 1.2.1 respectively.

Section 1.2.1—6 requires food for retail sale in a package to bear a label with the information listed in subsection 1.2.1—8(1), which includes a statement of ingredients. Subsection 1.2.1—6(1) lists exemptions to the general requirement to bear a label, including for whole or cut fresh fruit or vegetables in a package that does not obscure the nature or quality of the food.

1.3.2 International standards

In developing food regulatory measures, FSANZ must have regard to the promotion of consistency between domestic and international food standards. In terms of food safety, the relevant international standard setting body is the Codex Alimentarius Commission (Codex). Standards set by Codex provide a benchmark against which national food measures and regulations can be assessed. In certain situations however, FSANZ might receive an application to amend the Code for permission to use a new processing aid or food additive before an international standard exists.

There are also situations where domestic food standards will necessarily vary from international standards.

This could include circumstances where:

- new data for the domestic situation that was not available at the time the international standard was set becomes available for assessment
- the domestic environment (climate and growing conditions) results in different levels of risk from contaminants, natural toxicants or nutrient levels in foods
- domestic consumption patterns result in different dietary exposures
- particular manufacturing and production processes have been adopted to meet specific domestic requirements.

Mono- and diglycerides of fatty acids is a well-known and permitted food additive and has been used for many years in a large number of countries. It also has provisions for use in various food categories in the relevant standards of the international body Codex Alimentarius as detailed below.

It is permitted for various technological purposes in numerous countries. It is specifically permitted for use as a glazing agent in a number of these countries as noted below including Chile, China, the European Union, Japan, Mexico, Peru and the United States. A summary of

the assessments by international and country agencies is provided in section 3.7 of SD1. The below summary information relates to the regulation of the food additive as a glazing agent (or equivalent technological purpose).

1.3.2.1 Codex

In 2019, Codex added additional provision for the use of the food additive as a glazing agent to surface treat fresh fruits and vegetables in the General Standard for Food Additives (GSFA 2019). The provisions are for food categories 04.1.1.2 (Surface-treated fresh fruit) and 04.2.1.2 (Surface-treated fresh vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds) with the maximum level of use of GMP. The provision to surface treat fruit includes the note 'For use as a glaze where such surface treatment is allowed for application to the surface of fresh fruit'. The note related to the provision to surface treat fresh vegetables is 'For use as a glaze where such surface treatment is allowed for application to the surface of fresh vegetables, seaweeds or nuts and seeds'.

1.3.2.3 United States of America (USA)

The use of the food additive was self-determined to be Generally Recognized as Safe (GRAS) for the purpose of a glazing agent/surface-finishing agent for fresh fruits and vegetables under the requirements of the US Code of Federal Regulations (CFR) Title 21, section 170.205 (US CFR 2019). It was further determined by a voluntary GRAS notification, GNR 648 submitted by the applicant to the US Food and Drug Administration (FDA) to be applied as a glazing agent to fresh fruits and vegetables, in 2016 (US FDA 2016). The FDA provided a 'No questions' notice regarding this GRAS notification.

1.3.2.5 European Union (EU)

In 2019, the EU permitted the use of the food additive for the surface treatment specifically of the citrus fruits, melons, pineapples, bananas, papayas, mangos, avocados and pomegranates at use levels of GMP (Commission Regulation (EU) 2019).

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.

2 Summary of the assessment

2.1 Risk assessment

An assessment of data provided by the applicant has concluded that the food additive mono- and diglycerides of fatty acids performs the technological purpose of a glazing agent to extend the shelf life of various treated fresh fruits and vegetables. A comparison of results indicate mono- and diglycerides of fatty acids performs better than untreated product, and conventional waxes and resins. As an already permitted GMP food additive, it complies with

internationally accepted specifications of identity and purity, which are primary sources of specifications in Schedule 3.

FSANZ concludes that the composition of the food additive mono- and diglycerides of fatty acids (INS 471) does not differ significantly from dietary lipids and a numerical ADI is not required. Estimated mean dietary exposure for Australian and New Zealand populations to mono- and diglycerides of fatty acids if used as a glazing agent on surface treated fruits and vegetables represents 0.6-0.8% of mean total fat consumption, which is within normal daily variation.

2.2 Risk management

The risk assessment concluded that there are no safety concerns with extending the use of the GMP food additive mono- and diglycerides of fatty acids (INS 471) as a glazing agent for fresh fruit and vegetables.

Since food additives require specific permissions in the Code, the main risk management decision was whether to approve or reject the request to extend the use of the food additive for the specific purpose as a glazing agent for fresh fruits and vegetables. If the decision is to approve the extension of use, are there any conditions that need to be imposed and how best to add the permissions into the Code? The other aspects in the risk management decision are the regulatory options dealing with costs and benefits as analysed in section 2.4.1.1, which took into account the risk assessment conclusion of no safety concerns with the proposed extension of use of the food additive.

The technological purpose of extending the shelf life of treated fruits and vegetables has been assessed and concluded that such claims are supported (see section 2.4 of SD1).

To permit the extension of use of the food additive to treat fresh fruits and vegetables, it is proposed to add the permission for mono- and diglycerides of fatty acids (INS 471) to food sub subclass 4.1.2 (Surface treated fruits and vegetables) in the table to section S15—5, with the maximum permitted level of GMP. The permission relates to unprocessed fruits and vegetables since it sits under the subclass of 4.1 (Unprocessed fruits and vegetables). These products include fungi, nuts, seeds, herbs and spices since these food subclasses are both under the main food class of 4 (Fruits and vegetables (including fungi, nuts, seeds, herbs and spices)).

The consideration of labelling is provided in section 2.2.1.

2.2.1 Labelling considerations

Substances used as food additives are required to be declared in the list of ingredients on the label of most packaged foods for retail sale (see section 1.3.1.3 above).

Where a statement of ingredients is required on the label of a food, subsection 1.2.4—7(1) requires food additives to be declared in the statement of ingredients by one of the following methods: if the food additive can be classified in accordance with Schedule 7— the relevant class name followed in brackets by the name or code number of the food additive specified in Schedule 8; or else, the name of the food additive specified in Schedule 8.

Schedule 7 lists the prescribed food additive class names that can be used in the statement of ingredients. It is up to the food supplier to determine the relevant class name for declaring food additives in a statement of ingredients. 'Glazing agent' is included in the list of prescribed class names.

Schedule 8 lists the names and code numbers of food additives that are to be used for labelling purposes. In Schedule 8, 'Mono- and di-glycerides of fatty acids' is listed as a food additive name and 471 is listed as its code number.

For food for retail sale, there are some exemptions to the requirement to bear a label, including a statement of ingredients. These exemptions are set out in Standard 1.2.1 – Requirements to have labels or otherwise provide information. There is an exemption for whole or cut fresh fruit and vegetables (other than seed sprouts or similar products) in a package that does not obscure the nature or quality of the food. Mono- and di-glycerides of fatty acids would not need to be declared as an ingredient if an exemption applies.

Unpackaged food for retail sale is also not required to bear a label.

For sales of food to a caterer, a statement of ingredients must be either set out on the label of the food supplied to a caterer, or provided in documentation (subsection 1.2.1—16(1)).

FSANZ has not identified any reasons from a health or safety perspective to specifically require the declaration of mono- and di-glycerides of fatty acids to consumers and considers that the existing approach in the Code for the declaration of mono- and di-glycerides of fatty acids is appropriate. This approach is consistent with the current approach in the Code for other permitted food additives where there are no health or safety concerns, including those food additives currently permitted for surface treated fruits and vegetables such as carnauba wax (903) and shellac (904).

2.2.2 Risk management conclusion

The risk management conclusion is to permit the extension of use of the food additive mono- and diglycerides of fatty acids (INS 471) to treat fresh fruits and vegetables by adding the permission to the food sub subclass 4.1.2 (Surface treated fruits and vegetables) in the table to section S15—5, with the maximum permitted level of GMP.

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 the extension of use of the GMP food additive mono- and diglycerides of fatty acids as a glazing agent for fresh fruit and vegetables is unlikely to have a significant effect on international trade as there are provisions for this use in the internationally recognised Codex General Standard for Food Additives (GSFA). 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 in section 29 of the FSANZ Act:

2.4.1 Section 29

2.4.1.1 Consideration of costs and benefits

The Office of Best Practice Regulation (OBPR) granted FSANZ a standing exemption from the requirement to develop a Regulatory Impact Statement for permitting the use of food additives (OBPR correspondence dated 24 November 2010, reference number 12065). This standing exemption was provided as permitting food additives is machinery in nature and the use of the food additive is voluntary once the application has been successfully approved. This standing exemption relates to the introduction of a food additive to the food supply that has been determined to be safe.

FSANZ, however, has given consideration to the costs and benefits that may arise from the proposed measure for the purposes of meeting FSANZ Act requirements. 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 (paragraph 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. This analysis considers either the approval or rejection of the application (retain the status quo) to amend the Code to include the food additive INS 471 as glazing agent for fruits and vegetables.

The consideration of the costs and benefits in this section is not intended to be an exhaustive, quantitative economic analysis of the proposed measure. In fact, most of the effects that were considered cannot easily be assigned a dollar value. Rather, the assessment seeks to highlight the likely positives and negatives of moving away from the status quo by amending the Code as requested.

Costs and benefits of permitting INS 471 as glazing agent for fruits and vegetables.

Due to the voluntary nature of the permission, industry would only use this food additive where they believe a net benefit exists for them. There are already other glazing agents available to industry to apply to fruit and vegetables.

The use of INS 471, by prolonging the life of fruit or vegetables at appropriate quality, may reduce food waste and allow more environmentally friendly forms of transportation and/or less packaging in some cases, e.g. fewer plastic bags or plastic wraps needed to preserve freshness.

Costs of some fruit or vegetables may reduce for some consumers, e.g. because of less wastage in the supply chain. The fact that fruit or vegetables may last longer after being

purchased may also be of value to consumers. Some consumers may access a wider range of fruit and vegetables that previously had too short a shelf-life to be transported to and sold in certain markets.

Permitting the requested use of INS 471 may result in a small cost to government in terms of adding this to the current range of food additives that are monitored for compliance.

Conclusions from cost benefit considerations

FSANZ's current assessment is that the direct and indirect benefits that would arise from permitting the use of the INS 471 food additive most likely outweigh the associated costs. However, evidence-based information received by submitters may result in FSANZ arriving at a different conclusion.

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

There are no relevant New Zealand only Standards. Amendments are proposed to Schedule 15 which also applies to New Zealand.

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 in subsection 18(1) of the FSANZ Act during the assessment.

2.4.2.1 Protection of public health and safety

FSANZ undertook a safety assessment (SD1) and concluded there were no public health and safety concerns associated with extending the use of the GMP food additive mono- and diglycerides of fatty acids (INS 471) as a glazing agent to extend the shelf life of fresh fruits and vegetables.

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

The labelling considerations relating to the use of the food additive mono- and diglycerides of fatty acids (INS 471) as a glazing agent to extend the shelf life of fresh fruits and vegetables are discussed in section 2.2.1 – Labelling considerations.

2.4.2.3 The prevention of misleading or deceptive conduct

There were 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 used the best available scientific evidence when undertaking the risk analysis, which is provided in SD1. The applicant submitted a dossier of scientific studies and other technical information. This dossier, together with other technical information including scientific literature, was used in assessing the application.

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

There is a Codex Alimentarius Standard, being the General Standard for Food Additives (GSFA) which includes recent 2019 provisions for the use of the food additive as a glazing agent for the use on fresh fruits and vegetables.

The food additive is also permitted in Europe for the surface treatment of the following fruits, citrus fruits, melons, pineapples, bananas, papayas, mangos, avocados and pomegranates at use levels of GMP. It has been self-assessed as GRAS in the US, with GRN 648.

Permitting the use of the food additive for the proposed purpose of the application would therefore make the regulation in Australia and New Zealand consistent with both international food standards (Codex Alimentarius) and the US and Europe.

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

Permitting the use of the GMP food additive mono- and diglycerides of fatty acids (INS 471) as a glazing agent to extend the shelf life of fresh fruits and vegetables would bring Australia and New Zealand into line with other jurisdictions where it is already authorised for use. In this way, Australia and New Zealand will remain competitive with other international markets. This will also help foster continued innovation and improvements in delivering quality fresh fruit and vegetables to consumers and reduce wastage.

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

FSANZ identified no issues relevant to this objective.

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

The Ministerial Policy Guideline *Addition to Food of Substances other than Vitamins and Minerals*² 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

² <http://www.foodstandards.gov.au/code/fofr/fofrpolicy/pages/default.aspx>

- no nutrition, health or related claims are to be made in regard to the substance.

FSANZ determined that extending the use of the GMP food additive mono- and diglycerides of fatty acids (INS 471) as a glazing agent for fresh fruits and vegetables to extend their shelf life is consistent with these specific order policy principles for 'Technological Function'.

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.

4 References

CFR 2019, The United States Code of Federal Regulations, Title 21, section 170.205 Opportunity to submit a GRAS notice, The US Food & Drug Administration, https://gov.ecfr.io/cgi-bin/text-idx?SID=2ea781cc64b64b8f005029edd842ce96&mc=true&node=se21.3.170_1205&rqn=div8 Accessed June 2020

Commission Regulation (EU) 2012, No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council; <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32012R0231&qid=1422407801408&from=EN> Accessed June 2020

Commission Regulation (EU) 2019, No 2019/801 of 17 May 2019 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of mono- and diglycerides of fatty acids (E471) on certain fresh fruits <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019R0801&from=EN> Accessed June 2020

GSFA 2019, Codex Alimentarius General Standard for Food Additives, http://www.fao.org/gsfonline/docs/CXS_192e.pdf search for food additives at <http://www.fao.org/gsfonline/additives/search.html?lang=en> Accessed June 2020

JECFA 2017, Combined Compendium of Food Additive Specifications. Food and Agriculture Organization of the United Nations (FAO) Rome, Italy. Search for specific specifications available at: <http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-additives/en/> Accessed June 2020

US FDA 2016, The US Food & Drug Administration, GRAS GRN 648 (Monoglycerides), https://www.accessdata.fda.gov/scripts/fdcc/?set=GRASNotices&id=648&sort=GRN_No&order=DESC&startrow=1&type=basic&search=648 Accessed June 2020

The United States Pharmacopeia 2018 Food Chemicals Codex 11th Edition, United States Pharmacopoeial Convention, Rockville, MD. <http://publications.usp.org/> Accessed June 2020

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 A1191 – Mono- and diglycerides of fatty acids (INS 471) as glazing agent for fruits and vegetables) 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 this variation.

Dated [To be completed by Standards Management Officer]

[Insert name and title of Delegate]

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 clause 3 of the variation.

1 Name

This instrument is the *Food Standards (Application A1191 – Mono- and diglycerides of fatty acids (INS 471) as glazing agent for fruits and vegetables) 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 15 is varied by inserting in the table to section S15—5, under 4.1.2 Surface treated fruits and vegetables, in numerical order

471	Mono- and diglycerides of fatty acids	GMP
-----	---------------------------------------	-----

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 A1191 which seeks to extend the use of the food additive mono- and diglycerides of fatty acids (INS 471) as a glazing agent for fresh fruits and vegetables. 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 in Schedule 15 of the Code to permit the use of mono- and diglycerides of fatty acids (INS 471) as a glazing agent for fresh fruits and vegetables (food category 4.1.2).

3. Documents incorporated by reference

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

Existing provisions of the Code incorporate a document by reference that will prescribe identity and purity specifications for the food additive to be permitted by the draft variation. Section 1.1.1—15 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. Section S3—2 of Schedule 3 incorporates by reference the specifications listed in the Joint FAO/WHO Expert Committee on Food Additives (JECFA) Compendium of Food Additive Specifications (FAO/WHO 2017), the United States Pharmacopeial Convention (2018) Food Chemicals Codex (11th edition) and the Commission Regulation (EU) No 231/2012, specifications for food additives. These include specifications for this food additive.

4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of application A1191 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 the draft variation) will occur for a six-week consultation period.

The Office of Best Practice Regulation (OBPR) granted FSANZ a standing exemption from needing to develop a Regulatory Impact Statement for proposed variations of the Code to permit food additives or extending the use of existing food additives (OBPR correspondence dated 24 November 2010 - reference 12065). This standing exemption was provided as permitting food additives or extending the use of permitted food additives is likely to have only a minor impact on business and individuals. It is a minor, deregulatory change that allows for the introduction of a food product to the food supply that has been determined to be safe. Extending the use of the approved food additive is also voluntary.

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] amends the table to section S15—5 in Schedule 15 of the Code by inserting a new permission for Mono- and diglycerides of fatty acids (INS 471) under the food category 4.1.2 Surface treated fruits and vegetables.