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Approval report – Application A1191

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

Food Standards Australia New Zealand (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.

On 3 September 2020, FSANZ sought [submissions](#) on a draft variation and published an associated report. FSANZ received eight submissions (and one late submission).

FSANZ approved the draft variation on 3 February 2021. The Australia and New Zealand Ministerial Forum on Food Regulation was notified of FSANZ's decision on 5 February 2021.

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 (at Approval)

¹ <https://www.foodstandards.gov.au/code/applications/Pages/A1191.aspx>

Executive summary

Food Standards Australia New Zealand (FSANZ) has assessed an application from Apeel Sciences that sought 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 additive as a glazing agent was 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 with non-edible peel, 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 had concluded that the food additive mono- and diglycerides of fatty acids performed the technological purpose of a glazing agent to extend the shelf life of various treated fresh fruits and vegetables. A comparison of results indicated mono- and diglycerides of fatty acids performed better than untreated product, and conventional waxes and resins. Additional data supplied and assessed also concluded that the extension of shelf life did not diminish the nutritional or quality parameters of the treated produce. As an already permitted GMP food additive, it complied with internationally accepted specifications of identity and purity, which are primary sources of specifications in Schedule 3 of the Code.

FSANZ concluded that the composition of the food additive mono- and diglycerides of fatty acids did not differ significantly from dietary lipids and a numerical ADI was 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 represented 0.6-0.8% of mean total fat intake, which was within normal daily variation. The assessment also considered the potential for allergenicity due to the possible use of oils and fats derived from allergenic sources to produce the food additive. Based on the available evidence, there are unlikely to be allergenicity concerns related to use of the food additive, including extending its use as a glazing agent for fresh fruits and vegetables.

Eight submissions (plus one late supportive submission from an industry organisation) were received on FSANZ's assessment report. Four submissions were received from government agencies, two from consumer groups, one individual and one from an industry group. Three submissions opposed the application and raised a number of issues. Two submissions raised issues without offering a view on acceptance or not. Issues raised have been addressed in the report. They are summarised as consumers not knowing that a glazing agent has been added to the fresh fruit and vegetables relating to purchasing choices, allergen concerns related to the food additive, whether nutritional and quality parameters are diminished due to the shelf life extension and opposition to adding food additives to fresh produce.

From the risk assessment and risk management conclusions it was decided 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 sought 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 additive as a glazing agent is to extend the shelf life of the treated fresh produce and so reduce wastage through the food 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 Australia New Zealand Food Standards Code (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 classes of foods in the table to section S15—5. The relevant food sub subclass for this application is 4.1.2 – Surface treated fruits and vegetables, under the subclass 4.1 – Unprocessed fruits and vegetables. There is no permission for the food additive mono- and diglycerides of fatty acids for this food class.

Schedule 16 sets out the types of substances that may be used as food additives in any food at 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 classes due to listings within the table to section S15—5, however not the relevant food class 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 JECFA² 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, Food Standards Australia New Zealand (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 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

² the Joint FAO/WHO Expert Committee on Food Additives.

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 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 *Food Standards Australia New Zealand Act 1991* (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 report between 3 September 2020 and 15 October 2020.

FSANZ received eight submissions (and one late submission from an industry group which was supportive) from government agencies, industry groups, consumer groups and an individual. Issues raised in submissions have been addressed and supportive comments noted in Table 1 below.

A comment made in the late submission from an industry group made note that the FSANZ Act unfortunately cannot allow FSANZ to broaden the permission for using the glazing agent on fresh fruits and vegetables to also include nuts and seeds, which it noted was unfortunate.

FSANZ takes the opportunity to respond that this concern is unwarranted since the food class vegetables does include nuts and seeds. That is because the relevant food class 4 in the table to section S15—5 is 'Fruits and vegetables (including fungi, nuts, seeds, herbs and spices)'.

Table 1: Summary of issues and supportive comments raised in submissions and FSANZ’s response

Issue	Raised by	FSANZ response
ISSUES		
The ADI for the food additive has not been established for children.	Additive Free Kids	FSANZ concurs with the decision of JECFA ³ that a numerical ADI is not required for mono- and diglycerides (see SD1 for more detailed discussion). This conclusion applies to the general population including children.
The use of the food additive is unnecessary and is not needed for the end user (consumer). There is not a need for the use of glazing agents to prolong shelf life, as there is not normally a need for long transportation times; people to support local farmers and local production.	Additive Free Kids	The view expressed is not correct as a huge amount of Australian and New Zealand food has long transportation routes and times before being sold to consumers. This causes a large amount of food waste throughout the food supply chain, especially for fresh fruits and vegetables which have short shelf lives. Increasing the shelf life of fresh fruits and vegetables has benefits to all parties in the food supply chain, the primary producers, the transportation industry, the retailers and ultimately the consumers. This is an issue for all countries including Australia and New Zealand. There also is a long history of using permitted food additive glazing agents on fresh fruits and vegetables in Australia and New Zealand.
Consumers have the right to make informed purchasing choices to avoid this food additive if they desire. The applicant has indicated that it is possible to use stickers on treated products. Therefore FSANZ should require that all treated product is identified so that consumers can make informed purchasing choices. The food treated with the food additive will be unavoidable since in most cases the substance will not appear on any ingredient labels.	Additive Free Kids Food Intolerance Network	The food additive will be required to be declared in the statement of ingredients, however some foods are exempt from declaring a statement of ingredients (for example, unpackaged fruit and vegetables) (see section 1.3.1.3). This is consistent with the approach for ingredient labelling in the Code more generally, including other food additive glazing agents currently permitted to be used on fresh fruits and vegetables.

³ https://apps.who.int/iris/bitstream/handle/10665/41072/WHO_TRS_539.pdf?sequence=1&isAllowed=7 and <http://www.inchem.org/documents/jecfa/jecfamono/v05je44.htm>

Issue	Raised by	FSANZ response
<p>There is concern that recent scientific evidence has shown that emulsifiers have long term safety impacts on gut health. The applicant should be required to perform long term studies to prove that the food additive is safe for the proposed purpose and does not impact gut health.</p>	<p>Additive Free Kids</p>	<p>The application is for mono- and diglycerides as glazing agents rather than emulsifiers. JECFA has concluded that mono- and diglycerides used as emulsifiers do not differ significantly from dietary lipids. FSANZ has previously reviewed two publications that allege emulsifiers are detrimental to gut health; those of Chassaing et al (2015) and that of Lerner and Matthias (2015). FSANZ's response to those publications may be found in the Approval Report for A1137, at https://www.foodstandards.govt.nz/code/applications/Documents/A1137/Approval report.pdf</p>
<p>The same position should be taken as the European Union has taken in regards to permission of the use of this food additive; that is that it should only be permitted for fruits with hard peels that are not consumed. That is, it should not be permitted for cut fruit or any vegetables.</p>	<p>Additive Free Kids Food Intolerance Network</p>	<p>That is not the risk management decision FSANZ has taken. The reason for this decision is because the risk assessment conclusion is that adding the glazing agent to fresh fruit and vegetables is safe for the proposed purpose. The permission is not for cut fruit, only surface treatment of whole fruits and vegetables.</p>
<p>If the food additive is derived from a different source of fats and oils to that used by the applicant, such as a genetically modified (GM) source or animal origin then a new assessment should be required rather than a blanket permission via this application.</p> <p>The applicant has stated that its version of the food additive it uses is not a GM product and is suitable for vegetarians but other companies products that benefit from the applicant's permission may not be. How can consumers know where the glazing agent is sourced from (i.e. from a GM or animal source, or palm oil or other), which is important for consumers purchasing choices?</p> <p>Information is requested as to whether the source of the food additive is from palm oil as this information can be important for end consumers purchasing choices.</p>	<p>Additive Free Kids</p>	<p>What is required is that the food additive meets the relevant requirements in the Code including specification requirements, which is no different to the current requirements for this already approved and widely used food additive, and for all food additives.</p> <p>If the glazing agent was a GM food it would require approval as a GM food.</p> <p>As the permission for the food additive is not specific as to the source of fatty acids used to produce the food additive (animal or plant, or palm oil for example), labelling of the food additive as an ingredient would not assist with identification of the source. This approach is consistent with the labelling of other food additives in the Code.</p>
<p>Fruit and vegetables should be kept as</p>	<p>Additive Free Kids</p>	<p>Adding a simple glazing agent (not an emulsifier, since it is not acting</p>

Issue	Raised by	FSANZ response
<p>unprocessed products, as traditionally they have been. It is well recognised according to the NOVA⁴ classification of food that the application of emulsifiers to food results in ultra-processed food.</p>		<p>as an emulsifier for the proposed purpose) to the surface of fresh fruits and vegetables does not make them ultra-processed foods. Glazing agents such as waxes are already permitted and have been used on fresh fruits and vegetables for many years, e.g. waxes on apples.</p>
<p>No nutritional assessment has been performed to check that the extension of shelf life achieved by using the glazing agent has not come at the expense of nutritive value.</p> <p>Data is not provided on what the effect of coating fruit and vegetables with the glazing agent on flavour, texture and nutrient composition of the treated produce. It is concerned that the treatment could result in unacceptable flavour development or tissue softening so that consumers may be deceived about the eating quality of the treated produce.</p>	<p>Food Intolerance Network</p> <p>Queensland Health</p>	<p>There is commercial experience using the food additive as a glazing agent to extend the shelf life of fresh fruits and vegetables in the US as well in Europe to treat fruit where the peel is not consumed. Therefore there is a history of both safe use and also experience in extending the shelf life of the produce without compromising the quality or nutritional value of the produce. These factors were part of the reason why a nutritional risk assessment was not performed as part of FSANZ's assessment for this application.</p> <p>Additionally, confidential commercial information provided by the applicant provided more detailed data comparing treated versus untreated as well as conventional wax treatment of produce. Studies were conducted assessing the quality (taste and flavour as well as appearance, including internally and softening of the produce) as well as relevant nutritional parameters. The studies compared produce at either the same period of storage time, or at the comparable period of maturity (i.e. consumer acceptance linked to industry specific standards and specifications of quality). Examples of data included the physical appearance (external and internal) of avocados through the various stages of shelf life, as well as the fatty acid profiles. Comparable fatty acid profiles were obtained at the different stages of maturity noting the INS 471 glazed products had a longer acceptable shelf life for each period of ageing.</p> <p>Similar positive results were obtained for a variety of other produce including apples, nectarines, strawberries, tomatoes, mandarins, lemons and blueberries.</p>

⁴ NOVA, a food classification system developed by researchers at the University of Sao Paulo, Brazil. Explanation provided in this reference: Monteiro, C.A., Cannon, G., Lawrence, M., Costa Louzada, M.L. and Pereira Machado, P. 2019. *Ultra-processed foods, diet quality, and health using the NOVA classification system*. Rome, FAO. <http://www.fao.org/3/ca5644en/ca5644en.pdf>

Issue	Raised by	FSANZ response
<p>Given that the source of the oils used to produce the food additive may be peanut, soybean, sesame etc, it is questioned what are the allergen labelling requirements for allergens present. Do they contain allergens and are the allergens affected by the manufacturing process? Is the food additive derived from allergen plants exempt from labelling. Does the labelling regulation require amendment?</p>	<p>South Australia Health</p>	<p>The assessment of allergen issues related to this application are contained in section 3.5 of SD1. This section contains details relevant to the questions raised in the submission.</p> <p>The applicant has indicated that the source oils it uses to produce the food additive are not sources of major food allergens that require labelling.</p> <p>The assessment also considered the potential for allergenicity due to the possible use of oils and fats derived from allergenic sources to produce the food additive. Based on the available evidence and taking into account the purification processes used during production, there are unlikely to be allergenicity concerns related to use of the food additive, including extending its use as a glazing agent for fresh fruits and vegetables.</p>
<p>Diglycerides of fatty acids meet the definition of edible oils in Standard 2.4.1. If diglycerides of fatty acids are used as a food rather than a food additive with the function of glazing agent for fruits and vegetables, then they may not need to meet the specification referenced in the drafting of the proposal.</p>	<p>South Australia Health</p>	<p>This is noted as a comment rather than an issue or a question. The application has requested approval of an extension of use of the already permitted GMP food additive for the proposed purpose. It is being considered as a food additive, and so it needs to meet the specification requirements of the food additive.</p>
<p>This submitter raised concerns that fresh fruit and vegetables are proposed to be treated with such substances and that her child may inadvertently react to with anaphylaxis. The submission states that the medical profession is unable to identify which additives and preservatives the child is allergic to.</p>	<p>Private submitter</p>	<p>As noted in the response above, allergenicity is addressed in section 3.5 in SD1. The conclusion was that there was not an allergen concern related to use of the food additive, including extending its use as a glazing agent for fresh fruits and vegetables. The substance is a currently permitted food additive permitted and used in a wide variety of foods without known public health and safety concerns due to anaphylaxis. The application is an extension of use of this widely used food additive.</p>
<p>SUPPORT</p>		
<p>There is broad acceptance that the glycerides do not pose any health threat in themselves, nor does their composition or intake vary from that likely to exist in current diets. However it did raise three concerns (summarised and addressed above).</p>	<p>Food Intolerance Network</p>	<p>This preliminary comment is noted, along with the concerns raised which are summarised and addressed above.</p>

Issue	Raised by	FSANZ response
<p>It supports FSANZ's conclusions. That is, that use of the food additive performs the technological purpose of a glazing agent to extend the shelf life of treated fruits and vegetables. This is likely to reduce food waste. There are no public health and safety concerns with the proposed use. The labelling requirements for the coated fruits and vegetables are consistent with those that already apply for existing permitted glazing agents.</p>	<p>New Zealand Food Safety</p>	<p>These comments are noted.</p>
<p>It supports FSANZ's risk assessment conclusion that there are no public health and safety concerns with the application and so supports progression of its consideration. The summary of the reasons for this conclusion are provided.</p>	<p>Victorian Department of Health and Human Services and the Victorian Department of Jobs, Precincts and Regions</p>	<p>These comments are noted.</p>
<p>It is fully supportive of the application and the proposed draft amendments to the Code, to extend the use of the food additive to include fresh fruits and vegetables. The summary of the reasons for this conclusion are provided. Edible films and coatings on fresh produce have been around for nearly a century. Edible glazing products provide a safe means of extending and preserving products to limit food wastage and plastics use (as an alternative preservation means) and so contribute positively to the environment.</p>	<p>United Fresh New Zealand Incorporated</p>	<p>These comments are noted.</p>

2.2 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 performed 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 concluded 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.

The assessment also considered the potential for allergenicity due to the possible use of oils and fats derived from allergenic sources to produce the food additive. Based on the available evidence and taking into account the purification processes used during production, there are unlikely to be allergenicity concerns related to use of the food additive, including extending its use as a glazing agent for fresh fruits and vegetables.

2.3 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 was to approve the extension of use, then there may be conditions (such as labelling) that need to be imposed to add the permissions into the Code. The other aspects in the risk management decision were 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 was 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)).

2.3.1 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)).

This approach is consistent with the current approach for other permitted food additives including those food additives currently permitted for surface treated fruits and vegetables such as carnauba wax (903) and shellac (904).

2.3.2 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.

2.4 Risk communication

2.4.1 Consultation

Consultation is a key part of FSANZ's standards development process. 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. Public submissions were called to obtain the views of interested parties on issues raised by the application and the impacts of regulatory options. FSANZ acknowledges the time taken by individuals and organisations to make submissions on this application.

The draft variation was considered for approval by FSANZ taking into account the public comments received from the call for submissions.

2.5 FSANZ Act assessment requirements

When assessing this application and the subsequent development of a food regulatory measure, FSANZ had regard to the following matters in section 29 of the FSANZ Act.

2.5.1 Section 29

2.5.1.1 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 was 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 considered either the approval or rejection of the application (retain the status quo) to amend the Code to include the food additive INS 471 as a glazing agent for fruits and vegetables.

The consideration of the costs and benefits in this section was 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 sought 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 assessment was 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.

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

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

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 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.

2.5.2.2 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 are discussed in section 2.3.1 – Labelling considerations.

2.5.2.3 The prevention of misleading or deceptive conduct

There were 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 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](#)⁵ 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

⁵ <http://foodregulation.gov.au/internet/fr/publishing.nsf/Content/publication-Policy-Guideline-on-the-Addition-of-Substances-other-than-Vitamins-and-Minerals>

- 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 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 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/gsfaonline/docs/CXS_192e.pdf search for food additives at <http://www.fao.org/gsfaonline/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 Pharmacopeial Convention, Rockville, MD. <http://publications.usp.org/> Accessed June 2020

Attachments

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

Attachment A – Approved 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
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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.

The Authority 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 approved 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 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 included one round of public consultation following an assessment and the preparation of a draft Standard and associated report. Submissions were called for on 3 September 2020 for a six-week consultation period.

The Office of Best Practice Regulation (OBPR) granted FSANZ a standing exemption from

the requirement 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).