

**17 December 2015**  
**[32–15]**

Approval Report – Application A1100

## Maximum Permitted Level of Acesulphame Potassium in Chewing Gum

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Food Standards Australia New Zealand (FSANZ) has assessed an application made by The Wrigley Company Pty Ltd to FSANZ to increase the maximum permitted level of acesulphame potassium in chewing gum to align with international regulations and standardise formulations.

On 20 August 2015, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received six submissions.

FSANZ approved the draft variation on 3 December 2015. The Australia and New Zealand Ministerial Forum on Food Regulation<sup>1</sup> (Forum) was notified of FSANZ's decision on 16 December 2015.

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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<sup>1</sup> convening as the Australia and New Zealand Food Regulation Ministerial Council

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## Supporting documents

The following documents which informed the assessment of this Application are available on the FSANZ website at

<http://www.foodstandards.govt.nz/code/applications/Pages/A1100MaxPermit-Ace-KinChewing-Gum.aspx>

- SD1 Examples of how the MPL and unity principle affect the level of Ace K which can be added to chewing gum (at Approval)
- SD2 Risk and Technical Assessment Report (at Approval)

## Executive summary

The Wm. Wrigley Jr. Company, based in Australia, submitted an Application seeking permission to increase the maximum permitted level (MPL) of the intense sweetener food additive acesulphame potassium (Ace K), in chewing gum to 5000 mg/kg. Schedule 15 – Food additives in the revised Code<sup>2</sup>, permits Ace K in chewing gum at a maximum level of 2000 mg/kg.

The purpose of the requested increase in the MPL is to allow the sale of chewing gum in Australia and New Zealand which has a flavour profile (sweetness) similar to chewing gums available in overseas markets. Achieving the desired flavour profile in chewing gum often involves using a blend of food additives with similar technical functions (sweeteners) to Ace K.

The combination of the current MPL for Ace K in chewing gum and the need to adhere to the “unity principle<sup>3</sup>” restricts the flavour profile of chewing gum currently available in Australia and New Zealand. This means some chewing gum products available overseas are not available for sale in Australia or New Zealand. Increasing the MPL for Ace K in chewing gum to 5000 mg/kg will overcome the issue (there is no change to the requirement to adhere to the “unity” principle).

Ace K has been a permitted food additive in the Code, in a range of food categories, at a range of levels, for many years and is permitted to be added at a maximum level of 5000 mg/kg to chewing gum categories in other countries (Canada and Japan) and in the Codex Alimentarius General Standard for Food Additives (GSFA). Therefore, permission in the Code would result in consistency with international regulations and trading partners.

FSANZ’s risk assessment concluded that increasing the permitted levels of Ace K in chewing gum is technologically justified and safe.

The requested increase in the MPL of Ace K in chewing gum will apply to all chewing gum sold in Australia and New Zealand, not just those products marketed by the Applicant. Chewing gum manufacturers can choose to add Ace K at levels lower than the MPL under the general principle of Good Manufacturing Practice (GMP).

A call for submissions was publically released in August 2015. All six submissions supported the proposed draft variation, four from industry and two from Government departments.

All references to *the Australia New Zealand Food Standard Code* (the Code) in this approval report and related Supporting Documents (SDs) are to the revised Code which takes effect and replaces the current Code on 1 March 2016. This is because the gazettal of any variation is not expected until close to this date (if approved by the FSANZ Board and no review of that decision is requested by Ministers). FSANZ therefore considered it unnecessary to amend the current Code.

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<sup>2</sup> <http://www.foodstandards.gov.au/code/Pages/Revised-code-list-of-standards-and-schedules.aspx>

<sup>3</sup> This principle is explained in detail in the body of this summary and in SD1

# 1 Introduction

## 1.1 The Applicant

The Applicant was Wm. Wrigley Jr. Company (Australia) Pty Limited. The Wrigley Company (Australia) Pty Limited and the Wrigley Company (N.Z.) Limited are wholly owned subsidiaries of Wm. Wrigley Jr. Company. Wrigley is a subsidiary of Mars, Incorporated, one of the world's largest food companies.

## 1.2 The Application

This Application sought to increase the maximum permitted level (MPL) of acesulphame potassium (Ace K) in chewing gum. The increase enables The Wrigley Company and other chewing gum manufacturers to standardise formulations across their products and operations, and allow them to sell chewing gum products in Australia and New Zealand with flavour profiles (sweetness) which match products distributed in other overseas markets.

## 1.3 The current Standard

All references to the Code in this Report and related SDs are to the revised Code which takes effect and replaces the current Code on 1 March 2016. FSANZ considered it unnecessary to amend the current Code.

Ace K (INS 950) is a food additive with technological purposes as an intense sweetener and flavour enhancer. It has been a permitted food additive in the Code for many years, in a range of food categories at a range of levels. The table to section S15—5 details the various permissions.

The current permission for Ace K in chewing gum allows a MPL of 2000 mg/kg. This is listed under item 5 (Confectionery). Sub-item 5.2 (Sugar confectionery) contains a further permission for “bubble and chewing gum”. The permissions in item 5 apply to the sub-item 5.2 due to the hierarchical nature of food additive permissions in S15—5.

Section 1.3.1—6 of Standard 1.3.1 limits the amounts of additives in a food when two or more are used for the same technological purpose. This is often referred to as the “unity principle”. For intense sweeteners in chewing gum, the maximum amount of each additive is proportional to its MPL, as stated in sub-item 5.2 of the table to section S15—5 of Schedule 15, with the sum of the proportions of all the additives not exceeding 1.

To produce a chewing gum product that meets both flavour and format preferences, it is necessary to use blends of sweeteners, which means it is necessary to apply the “unity principle”. As a result of the current MPL in the Code for Ace K and the need to apply the “unity principle”, some chewing gum products available in overseas markets are not permitted in Australia or New Zealand.

### 1.3.1 International and National Standards

There are permissions for the use of Ace K as an intense sweetener in chewing gum in food regulations around the world, as noted below.

#### 1.3.1.1 Codex

Since 2007, the Codex Alimentarius General Standard for Food Additives (Codex Stan 192-1995) has permitted the addition of Ace K to chewing gum to a maximum level of 5000 mg/kg.

There are two notes attached to this permission. The first (note 161) is clarification that the permission is subject to national legislation of the importing country, in particular with respect to justification for the use of additives. This Codex justification is consistent with the requirement in the written policy guideline “Addition to Food Substances other than Vitamins or Minerals”, formulated by the Ministerial Council<sup>4</sup>, that a food additive must be technologically justified.

The second note (note 188) states “Not to exceed the maximum use level for acesulphame potassium [INS 950] singly or in combination with aspartame-acesulphame salt [INS 962].” The second part of this statement is similar to the “unity principle” in the Code, but only applies when Ace K is used in combination with aspartame-acesulphame salt i.e. it does not apply when Ace K is used in combination with other food additive sweeteners such as aspartame.

#### **1.3.1.2 European Union (EU)**

The European Union Commission Regulation (EU) No. 1129/2011 permits the use of Ace K in chewing gum, with no added sugar, up to a maximum level of 2000 mg/kg. When used as a food additive in chewing gum, for sweetening purposes, there is no unity-type principle. Therefore, even when Ace K is added to chewing gum as part of a blend of intense sweeteners, the only limit is the maximum level of 2000 mg/kg, i.e. the amount used in a blend is not restricted by the presence of other additives performing a sweetening function.

#### **1.3.1.3 United States of America**

The United States Food and Drug Administration (2014) Code of Federal Regulations Chapter 21, CFR 172.800 permits the use of Ace K in foods in accordance with GMP and in an amount not to exceed that reasonably required to meet its technical function in food.

#### **1.3.1.4 Canada**

Health Canada Food and Drug Regulations (2013), Division 16, Table IX, item A.01 permits the use of Ace K in chewing gum at a maximum level of 0.5% (5000 mg/kg). There is no unity-type principle.

#### **1.3.1.5 Japan**

Japan’s Food Sanitation Act,(2015), Enforcement Regulations, Article 12, permits the use of Ace K in chewing gum up to a MPL of 5000 mg/kg. There is no unity-type principle.

### **1.4 Reasons for accepting the Application**

The Application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2)
- 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.

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<sup>4</sup> Now known as the Australia and New Zealand Ministerial Forum on Food Regulation (convening as the Australia and New Zealand Food Regulation Ministerial Council)

## 1.6 Decision

Amending the current MPL for Ace K in chewing gum to a higher level of 5000 mg/kg is safe, technologically justified and would allow currently prohibited chewing products into Australia and New Zealand.

Therefore, the draft variation was approved as proposed following the assessment, see Attachment A. The variation takes effect on 1 March 2016.

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 Legislative Instruments.

The revision is made to the revised Code only because the gazettal of the draft variation is not expected to occur until close to the date the revised code comes into effect (if no review of the FSANZ decision is requested by Ministers).

## 2 Summary of the findings

### 2.1 Summary of issues raised in submissions

Six submissions were received in response to the call for submissions released in August 2015. All submitters supported amending the Code to permit an increase in the MPL for Ace K in chewing gum, as requested by the Applicant.

**Table 1: Summary of issues**

Issue	Raised by	FSANZ response
<b>There are no public health and safety concerns associated with the proposed increase in the MPL for Ace K in chewing gum.</b>	Australian Food and Grocery Council Ai Group, Confectionery Sector NZ Food & Grocery Council NZ Ministry for Primary Industries Victorian Department of Health and Human Services and the Victorian Department of Economic Development, Jobs, Transport & Resources	FSANZ's own assessment confirms that the amendment to the Code presents no public health or safety concerns.
<b>The proposed increase is technologically justified.</b>	Ai Group, Confectionery Sector NZ Ministry of Primary Industries	Comment noted. FSANZ's own assessment is that the proposed amendment is technically justified.

Issue	Raised by	FSANZ response
<p><b>Permission would encourage innovation, growth opportunities and global competitiveness.</b></p> <p><b>The unity rule remains unchanged which means Australia/New Zealand regulations remain more restrictive than other countries which do not apply a unity type principle.</b></p> <p><b>FSANZ cost benefit analysis supports the regulatory variation.</b></p>	<p>Ai Group, Confectionery Sector NZ Food &amp; Grocery Council</p>	<p>Noted, see section 3 below.</p> <p>Changes to the unity principle are out of scope of this application. In line with the risk assessment, approval has been given for MPL for Ace K in chewing gum to be increased 5000 mg/kg which will allow for a greater amount of Ace K than is currently permitted to be added to sweetener blends.</p> <p>Comment noted.</p>
<p><b>The proposal to increase the MPL for Ace K in chewing gum is supported.</b></p>	<p>Food Technology Association of Australia</p>	<p>Comment noted</p>
<p><b>The proposed increased level for Ace K in chewing gum aligns with the Codex General Standard for Food Additives and that in place in several other countries.</b></p>	<p>Ai Group, Confectionery Sector New Zealand Food &amp; Grocery Council NZ Ministry for Primary Industries</p>	<p>Noted, see section 3 below.</p>
<p><b>The proposal to increase the MPL for Ace K in chewing gum is also supported on the basis of the benefits to oral care; provision of greater choice for consumers on low calorie diets and diabetics; potential for industry growth.</b></p>	<p>N Z Food &amp; Grocery Council</p>	<p>Comment noted.</p>
<p><b>The proposal to increase the MPL for Ace K in chewing gum is supported.</b></p>	<p>Food Technology Association of Australia</p>	<p>Comment noted</p>

## 2.2 Risk assessment

FSANZ considers the Acceptable Daily Intake (ADI) of 0–15 mg Ace K per kg bodyweight established by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) to be a suitable health-based guidance value to compare with estimated dietary exposure. No subsequent studies were located which could be considered to affect this ADI.

A dietary exposure assessment was undertaken using food consumption data from the available Australian and New Zealand national nutrition surveys, and data on Australia/New Zealand consumption of foods containing intense sweeteners. Using conservative assumptions to account for the additional dietary exposure resulting from the proposed increase in the MPL for chewing gum, estimated dietary exposures for high (90<sup>th</sup> percentile) consumers were 6–20% of the ADI for the population groups assessed.

FSANZ concluded that the proposed increase in the MPL for Ace K in chewing gum from 2000 mg/kg to 5000 mg/kg would result in estimated dietary exposure to Ace K that is well below the ADI of 15 mg/kg bw. Therefore, there are no public health and safety concerns associated with the proposed increase in the MPL for Ace K in chewing gum.

FSANZ's risk assessment is provided in SD2. It varies slightly from that consulted on due to the correction of minor typographical and formatting errors.

## **2.3 Risk management**

### **2.3.1 Levels of addition**

This application is an extension to the use of Ace K in chewing gum. No public health or safety issues were identified associated with this extended use.

Ace K is commonly used with other sweeteners in chewing gum and as a consequence the "unity principle" provision (see section 1.3.1 above and SD1) applies. As a result of the unity principle, it is unlikely that Ace K will ever be incorporated in chewing gum at the proposed revised MPL of 5000 mg/kg. As shown in the example in SD1, the maximum level of Ace K in chewing gum is more likely to be in the region of 2000 mg/kg i.e. similar to that permitted currently in the Code. However, increasing the MPL for Ace K in chewing gum to 5000 mg/kg allows for a greater proportion of Ace K than is currently permitted to be added to sweetener blends.

Considering the actual level of Ace K in chewing gum is likely to be considerably lower than 5000 mg/kg, the risk and dietary exposure assessments undertaken in support of this Application can be taken as "worse-case". This, in turn, gives confidence that the risks to public health and safety from increasing the Ace K MPL in chewing gum are being adequately managed by the outcomes of this Application.

Therefore, increasing the permission for Ace K in chewing gum up to a MPL of 5000 mg/kg is justified.

### **2.3.2 Revised MPL and bubble gum**

As chewing gum and bubble gum are classified under the same item (a sub-item of confectionery), the proposed increase in the Ace K MPL in chewing gum will also apply to bubble gum. In the absence of any identified public health or safety issues associated with the proposed extended use in chewing gum and noting that dietary exposure assessments undertaken in support of this Application can be taken as "worse-case", FSANZ considers the risks to public health and safety from increasing the MPL in bubble as well as chewing gum are adequately managed by the outcomes of this Application.

### **2.3.3 Specification**

A specification already exists and no modification is required.

### **2.3.4 Analytical methods**

Analytical methods for identifying and quantifying Ace K in foods and beverages, as well methods that can separate and quantify other intense sweeteners used in combination with Ace K, already exist. Therefore, no changes were necessary as part of this Application.

### **2.3.5 Labelling**

Ace K when used as a food additive, is currently required to be declared in the list of ingredients on the label of most packaged foods in accordance with section 1.2.4—7. This requires the class name *sweetener* to be declared, followed by the prescribed name acesulphame potassium, or code number 950 in brackets. These existing labelling provisions will continue to allow consumers to identify whether Ace K has been added to a packaged food.



Based on the risk assessment conclusions, there are no specific risk management measures needed for the increase to the MPL and consumers will be informed of Ace K presence in food via mandatory labelling.

## **2.4 Risk communication**

FSANZ applied a basic communication strategy to this Application, involving one call for submissions. All calls for submissions were notified via the Food Standards Notification Circular, media release, FSANZ's social media tools and Food Standards News. The Applicant, individuals and organisations that made submissions on this Application were notified at each stage of the assessment. Subscribers and interested parties were also notified via email about the availability of reports for public comment.

FSANZ's decision to approve the draft variations has been notified to the Australia and New Zealand Ministerial Forum on Food Regulation<sup>5</sup> (Forum). If the decision is not subject to a request for a review, the Applicant and stakeholders, including the public, will be notified of the gazettal of the variations to the Code in the national press and on the FSANZ website.

### **2.4.1 Consultation**

Consultation is a key part of FSANZ's standards development process. After assessing the Application, public submissions were called for from 20 August to 1 October 2015, to obtain the views of interested parties on the impacts of the regulatory options. Six submissions were received; four from the food industry and two from Government agencies. All submitters supported the Application.

FSANZ acknowledges the time taken by individuals and organisations to make submissions on this Application. Every submission is considered by the FSANZ Board. All comments are valued and contribute to the rigour of our assessment.

## **2.5 Impact analysis**

The Office of Best Practice Regulation, in a letter dated 31 March 2015 (reference 18791), advised that a Council of Australian Government Regulatory Impact Statement was not required for this matter.

Based on the information provided, the OBPR advised that the proposal is likely to have a minor regulatory impact on business, community organisations or individuals. Given the market characteristics, the proposed change is not likely to have significant competition impacts and any change by businesses in response to changes to the Code, if gazetted, will be voluntary.

However, FSANZ undertook a limited qualitative impact analysis.

Two regulatory options were considered:

- (1) approval of a draft variation to the revised Code (either with or without amendment following the call for submissions) to permit the requested increase of the MPL for Ace K in chewing gum
- (2) reject the draft variation.

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<sup>5</sup> convening as the Australia and New Zealand Food Regulation Ministerial Council

The likely impacts of these options were considered, but this consideration was not intended to be an exhaustive, quantitative economic analysis. Rather, the qualitative effects of each option are described below, and are deliberately limited to broad areas such as trade and consumer choice.

**Option 1 – approval of a draft variation to the revised Code**

Sector	Costs or benefits
Consumers	Consumers are likely to benefit from an increase in the MPL for Ace K in chewing gum as it would allow the sale of gums with flavour profiles which are similar to those available in overseas markets. The Applicant claims that chewing gums with a higher level of Ace K have enhanced flavour and longevity compared with chewing gums currently sold in Australia and New Zealand.
Industry	Approval of the draft variation could benefit all chewing gum manufacturers and importers in Australia and New Zealand. It would enable them to manufacture for sale in Australia and New Zealand, or import, chewing gum with flavour profiles similar/the same as those available overseas, which may be more desired by the consumer due to the claimed superior flavour profile.
Governments	There should be no impact on government enforcement agencies since Ace K is already permitted to be added to various food categories, including chewing gum. The method of analysis of its presence in food is unchanged.

**Option 2 – reject the draft variation**

Sector	Costs or benefits
Consumers	There are no benefits to consumers with this option. They would not have the option of purchasing chewing gum products with flavour profiles similar to those currently available overseas, which they might prefer to current profiles available in Australia and New Zealand.
Industry	Industry would not be able to sell chewing gum which is claimed to have superior flavour profiles. They could be at a disadvantage compared to international competitors.
Governments	There would be no direct impacts on government agencies.

FSANZ considered that Option 1 to permit the requested increase in the MPL for Ace K in chewing gum as the preferred option and therefore approved the draft variation to the revised Code.

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

**2.6 FSANZ Act assessment requirements**

**2.6.1 Section 29**

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

**2.6.1.1 Cost benefit analysis**

As explained in section 2.5, FSANZ conducted a cost benefit analysis which concluded that the benefits that would arise from the proposed food regulatory measure will outweigh the costs to the community, Government or industry that may arise from that measure.

### **2.6.1.2 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. See section 2.5.

### **2.6.1.3 Any relevant New Zealand standards**

Schedule 15 applies in both Australia and New Zealand.

### **2.6.1.4 Any other relevant matters**

Other relevant matters are considered below.

## **2.6.2 Subsection 18(1) considerations**

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

### **2.6.2.1 Protection of public health and safety**

Ace K has been a permitted food additive in the Code for many years, in a range of food categories as detailed in Schedule 15. FSANZ has undertaken a safety assessment (see SD2 and section 2.2 above) and concluded that there are no public health and safety concerns from increasing the MPL from 2000 mg/kg to 5000 mg/kg in chewing gum.

### **2.6.2.2 The provision of adequate information relating to food to enable consumers to make informed choices**

This variation to the Code does not vary the generic labelling requirements applicable to chewing gum, to provide information to consumers.

### **2.6.2.3 The prevention of misleading or deceptive conduct**

FSANZ has not identified any relevant issues relating to the prevention of misleading or deceptive conduct for this Application.

## **2.6.3 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**

This Application was assessed using the best available scientific evidence. The Applicant submitted information on scientific studies in support of the Application. Other resource material including general technical information was also used to assess this Application

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

The amendment (food additive permission) makes the Australian and New Zealand regulations for production of chewing gum more consistent with food standards in other countries (see Section 1.3.1)

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

The variation is expected to have a positive effect on the local chewing gum industry as it will allow the manufacture of chewing gum with taste profiles which are currently not available in Australia or New Zealand but are available in overseas markets.

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

Not applicable.

- **any written policy guidelines formulated by the Ministerial Council<sup>6</sup>**

The Policy Guideline 'Addition to Food of Substances other than Vitamins and Minerals'<sup>7</sup> includes specific order policy principles for substances added to achieve a solely technological function, such as food additives. These specific order policy principles state that permission should be granted where:

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

FSANZ determined that permitting a higher MPL of the food additive Ace K in chewing gum is consistent with these specific order policy principles.

### 3 References

Codex Alimentarius (2014) General Standard for Food Additives, CODEX STAN 192-1995 (Revision 2014), Acesulphame Potassium, food category number 05.3 Chewing gum Table one, page 67. [http://www.codexalimentarius.net/gsfaonline/docs/CXS\\_192e.pdf](http://www.codexalimentarius.net/gsfaonline/docs/CXS_192e.pdf) Accessed on 17 July 2015

European Commission (2011) Commission Regulations (EU) No 1129/2011 of 11 November 2011 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council by establishing a Union list of food additives. Part E, Authorised food categories and conditions of use in food categories Category number 05.3, Chewing gum Page 81 <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:295:0001:0177:En:PDF> Accessed on 17 July 2015

Health Canada (2013) Notice of Modification to the Lists of Permitted Sweeteners to increase the Permitted Maximum Levels of the Use for Acesulfame Potassium in Chewing Gum and for Sucralose in Chewing gum and Breath Freshener Products Regulated as Food. Ottawa (ON): Health Canada, Bureau of Chemical Safety, Food Directorate, Health Products and Food Branch. <http://www.hc-sc.gc.ca/fn-an/consult/nom-adm-0006/document-consultation-eng.php>

List of Permitted Sweeteners (current version, issued date 24 April 2014) <http://www.hc-sc.gc.ca/fn-an/securit/addit/list/9-sweetener-edulcorant-eng.php> Accessed on 17 July 2015

<sup>6</sup> Now known as the Australia and New Zealand Ministerial Forum on Food Regulation (convening as the Australia and New Zealand Food Regulation Ministerial Council)

<sup>7</sup> <http://www.foodstandards.gov.au/code/fofr/fofrpolicy/pages/default.aspx>

Japan's Food Sanitation Act,(2015), Enforcement Regulations, Article 12, permit the use of Ace K in chewing gum up to a MPL of 5000 mg/kg. Page 13, non-nutritive Sweeteners at [http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/7bd44c20b0dc562649256502001b65e9/8a4352b95978b195492569990007fbaa/\\$FILE/Standards%20for%20Use%2015May%2019.pdf](http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/7bd44c20b0dc562649256502001b65e9/8a4352b95978b195492569990007fbaa/$FILE/Standards%20for%20Use%2015May%2019.pdf) Accessed 20 July 2015

US FDA (2014) Code of Federal Regulations Chapter 21, CFR 172.800, Subchapter B, Food for Human Consumption (continued), Part 172, Sec 172.800 Acesulfame Potassium. <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=172.800> Accessed on 17 July 2015

## **Attachments**

- A. Approved draft variation to the *Australia New Zealand Food Standards Code* (commencing 1 March 2016)
- B. Explanatory Statement

## **Attachment A – Approved draft variation to the revised *Australia New Zealand Food Standards Code* (commencing 1 March 2016)**



### **Food Standards (Application A1100 – Maximum Permitted Level of Acesulphame Potassium in Chewing Gum) Variation**

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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 Standard commences on the date specified in clause 3 of this variation.

Dated [To be completed by Standards Management Officer]

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

**Note:**

This variation will be published in the Commonwealth of Australia Gazette No. FSC **XX on XX Month 20XX**.

**1 Name**

This instrument is the *Food Standards (Application A1100 – Maximum Permitted Level of Acesulphame Potassium in Chewing Gum) Variation*.

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

The Schedule varies Schedule 15 in the *Australia New Zealand Food Standards Code*.

**3 Commencement**

This instrument commences on 1 March 2016 immediately after the commencement of Standard 5.1.1 – Revocation and transitional provisions – 2014 Revision.

**Schedule**

**[1] The table to section S15—5** is varied by

[1.1] omitting “See Note, below”, where first occurring in item 5, substituting “Not for bubble gum and chewing gum.”

[1.2] omitting “950,” from the Note to item 5

[1.3] inserting in subitem 5.2.1 after the entry for additive 321

“

950	Acesulphame potassium	5 000	See Note, below <b>Note</b> Section 1.3.1—5 does not apply
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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 A1100 which sought to increase the maximum permitted level (MPL) of acesulphame potassium (Ace K) in chewing gum to align with the international regulations and so standardise formulations. 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<sup>8</sup>, 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 *Legislative Instruments Act 2003*.

### **2. Purpose**

The Authority has approved a draft variation to Schedule S15—5 which would allow a higher than currently permitted MPL for Ace K, a food additive (sweetener and flavour enhancer) in chewing gum. Permitting this higher level in chewing gum would enable manufacturers and importers to sell chewing gum in Australia and New Zealand with taste profiles which are matched with those currently available in overseas markets.

The approved draft variation would provide consistency with international regulations and trading partners, and facilitate the production and importation of currently prohibited chewing gum products in Australia and New Zealand.

### **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 A1100 included one round of public consultation following an assessment and the preparation of a draft variation and associated report. A call for submissions (including the draft variation) occurred for a six-week consultation period.

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<sup>8</sup> convening as the Australia and New Zealand Food Regulation Ministerial Council



A Regulation Impact Statement was not required because the proposed variation to section S15—5 is 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] amends the table to section S15—5 in Schedule 15 Food Additives.

Item [1.1] amends the existing entry for Acesulphame potassium in item 5 of the table. The amendment provides that entry does not apply to bubble gum or to chewing gum. This is to reflect the amendment made by item [1.3] of the draft variation.

Item [1.2] omits the reference “950,” from the Note to item 5 in the table. This is to reflect the amendments made by items [1.1] and [1.3] of the draft variation.

Item [1.3] amends subitem 5.2.1 of the table. It inserts a permission after the entry in that subitem for additive 321 for the use of Acesulphame potassium (INS number 950) as a food additive in bubble gum and chewing gum subject to a maximum permitted level of 5000 mg/kg.