

**26 October 2016**  
**[26–16]**

Approval report – Application A1113

## Extension of the use of Propionates in Processed Meat

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Food Standards Australia New Zealand (FSANZ) has assessed an application made by Axiome Pty Ltd on behalf of Kemin Industries (Asia) Pte Ltd to extend the use of propionates as anti-microbial preservatives in processed meat products.

On 29 June 2016, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received five submissions, along with one late submission, which all supported FSANZ's report and draft variation.

FSANZ approved the draft variation on 19 October 2016. The Australia and New Zealand Ministerial Forum on Food Regulation (Forum) was notified of FSANZ's decision on 25 October 2016.

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 which informed the assessment of this Application is available on the FSANZ website at

<http://www.foodstandards.govt.nz/code/applications/Pages/A1113Propionates-in-Processed-Meat.aspx>:

SD1 Risk and Technical Assessment Report

# Executive summary

Axiome Pty Ltd, on behalf of Kemin Industries (Asia) Pte Ltd, submitted an Application seeking permission to extend the use of propionic acid and its calcium, sodium and potassium salts (hereon collectively referred to as “propionates”<sup>1</sup>), to processed and processed comminuted meat, poultry and game products (collectively referred to as “processed meat, poultry and game”).

The justification for the Application was to have alternative anti-microbial preservatives to limit microbial growth, in particular *Listeria monocytogenes* in processed meat, poultry and game products.

The Applicant sought approval for the use of propionates as a preservative, under the conditions of good manufacturing practice (GMP), in the following food categories of the *Australia New Zealand Food Standards Code* (the Code):

- (i) processed meat, poultry and game products in whole cuts or pieces
- (ii) processed comminuted meat, poultry and game products.

In the Code, all four propionates are currently permitted to be added to breads and bakery products and flour products, including noodles and pasta (at either GMP or 4000 mg/kg, depending on the product). Sodium propionate and calcium propionate are also permitted, under conditions of GMP, in a variety of other food categories, including oil emulsions, fruit and vegetable products, formulated beverages, and sauces. Propionic acid, sodium propionate and calcium propionate are permitted to be added to solid formulated supplementary sports foods at a maximum permitted level of 400 mg/kg.

In the Codex General Standard for Food Additives (GSFA) propionates are currently listed for use under the conditions of GMP in the two processed meat food categories which are the subject of the Application.

The United States Food and Drug Administration (USFDA) permits the use of propionic acid and its sodium salt, as preservatives, in “ready to eat” meat and poultry up to 0.5% (5,000 mg/kg).

Propionic acid is a normal intermediary metabolite in humans and is naturally present in a wide variety of foods e.g. cheese and butter. Propionic acid and its sodium, calcium and potassium salts have a long history of use as food additives. Assessments by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and the European Food Safety Authority (EFSA) have concluded that there is no evidence of systemic toxicity resulting from oral exposure to propionates. Establishment of an acceptable dietary intake (ADI) expressed in numerical form was therefore not deemed necessary by JECFA and EFSA; FSANZ agreed with this conclusion. Due to the absence of systemic toxicity resulting from oral exposure to propionates, a dietary exposure assessment was not conducted for this Application.

Evidence submitted in support of this Application provided adequate assurance that propionates fulfil the stated technological function as anti-microbial preservatives in processed meat, poultry and game products. Any additional dietary exposure to propionates resulting from their proposed use as food additives in processed meat, poultry and game products presented no identified public health and safety concerns.

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<sup>1</sup> Use of the term propionates in this document refers collectively to propionic acid (INS 280), sodium propionate (INS 281), potassium propionate (INS 282) and calcium propionate (INS 283).

The use of propionates under the proposed conditions of GMP is not expected to affect the taste of the processed meat, poultry and game products.

The FSANZ Board has approved a draft variation to permit the use of propionates as anti-microbial preservatives in processed meat, poultry and game products in both food categories 8.2 and 8.3 in the table to section S15—5.

# 1 Introduction

## 1.1 The Applicant

The Applicant is Kemin Industries (ASIA) Pte Ltd. Kemin Industries (ASIA) Pte Ltd is part of Kemin Industries Inc. who manufactures speciality ingredients for global food and feed industries, including food technologies. Kemin Industries Inc. has headquarters in Iowa, USA. In Australia and New Zealand, Kemin Industries Inc. are represented by Hawkins Watts Ltd.

## 1.2 The Application

This Application sought to extend the approval for use of the anti-microbial food preservatives, propionates, under conditions of good manufacturing practice (GMP), to certain processed meat, poultry and game products. Allowing this extension provides an additional risk management tool for the control of microbial activity due to *Listeria monocytogenes*, in the aforementioned products.

Approval of this Application gives all meat processing industries in Australia and New Zealand the option to use these propionates as preservatives in processed meat, poultry and game products.

## 1.3 The current Standard

Propionic acid (INS 280), calcium propionate (INS 282), potassium propionate (INS 283) and sodium propionate (INS 281) are food additives with the technological purpose of anti-microbial preservatives. They have been permitted food additives in the *Australia New Zealand Food Standards Code* (the Code) for many years, in a range of food categories at a range of levels. A summary of the current permissions, from the table to section S15—5 within Schedule 15, is listed in Table 1:

**Table 1: Current permissions for propionates in the Code**

Propionate	Food category number and name	Condition
Propionates <sup>2</sup>	7 Bread and bakery products	Up to an MPL <sup>3</sup> of 4000 mg/kg
Propionates	6.4 Flour products, including noodles and pasta	Up to an MPL of 2000 mg/kg
Sodium and calcium propionate	2.2.2 oil emulsions (80% oil)	GMP
Sodium and calcium propionate	4.3.4 fruit and vegetable spreads (including jams, chutneys and related products)	GMP
Sodium and calcium propionate	14.1.2 fruit and vegetable juices and fruit and vegetable juice products	GMP
Sodium and calcium propionate	14.1.4 formulated beverages	GMP
Sodium and calcium propionate	20.2.0.4 sauces and toppings, including mayonnaises and salad dressings	GMP
Propionic acid and its sodium and calcium salts	13.1.4.1 Solid formulated supplementary sports foods	Up to an MPL of 400 mg/kg

<sup>2</sup> Propionates includes the four substances, INS 280, 281, 282 and 283

<sup>3</sup> MPL – Maximum Permitted Level

### 1.3.1 Codex standard

The Codex General Standard for Food Additives (GSFA)<sup>4</sup> permits the use of propionates, as food additives (preservatives), under the conditions of GMP in the following two food categories:

- 08.2 – Processed meat, poultry, and game products in whole pieces or cuts, and
- 08.3 – Processed comminuted meat, poultry, and game products.

### 1.3.2 The United States Food and Drug Administration

The United States Food and Drug Administration (US FDA) permits the use of propionic acid (§184.1081) and sodium propionate (§184.1784)<sup>5</sup> in the Code of Federal Regulations (CFR), Title 21 (Food and Drugs). These substances are classified as generally recognized as safe (GRAS) anti-microbial agents (preservatives) used at GMP in different food products including meat products (defined in §170.3(n)(29)). The United States Department of Agriculture (USDA) FSIS Directive 7210.1 (Revision 15 of 30 April 2013)<sup>6</sup> permits the use of sodium propionate and propionic acid to treat ready-to-eat meat and poultry, where antimicrobials are permitted. The limit for treatment is up to 0.5% (by weight of total formulation).

### 1.3.3 European Union

The European Food Safety Authority (EFSA) Panel on Food Additives and Nutrient Sources Added to Food (ANS) released an assessment in August 2016<sup>7</sup> concluding that sodium propionate as an antimicrobial agent food additive used in treating meat preparations, processed meat and fish up to 5,000 mg/kg “would not be of safety concern”. The European Commission will need to consider whether to approve the extension of use of this food additive.

## 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 was assessed under the General Procedure.

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<sup>4</sup> Codex Alimentarius General Standard for Food Additives, CODEX STAN 192-1995 (Revision 2016), Table 3, food category numbers 08.2 Processed meat, poultry, and game products in whole pieces or cuts, 08.3 processed comminuted meat, poultry, and game products.

<http://www.fao.org/gsfaonline/additives/search.html?lang=en> Accessed on 25 August 2016.

<sup>5</sup> US FDA 21 CFR 184 [http://www.ecfr.gov/cgi-bin/text-](http://www.ecfr.gov/cgi-bin/text-idx?SID=5da6fa0bb90c2f8f8548889522619fdc&mc=true&node=pt21.3.184&rqn=div5)

<http://www.ecfr.gov/cgi-bin/text-idx?SID=5da6fa0bb90c2f8f8548889522619fdc&mc=true&node=pt21.3.184&rqn=div5> Accessed 25 August 2016

<sup>6</sup> United States Department of Agriculture Food Safety and Inspection Service, FSIS Directive 7210.1 (Revision 15 of 30 April 2013) Safe and suitable ingredients used in the production of meat, poultry, and egg products

[http://www.fsis.usda.gov/wps/wcm/connect/7f981741-94f1-468c-b60d-b428c971152d/7120\\_68.pdf?MOD=AJPERES](http://www.fsis.usda.gov/wps/wcm/connect/7f981741-94f1-468c-b60d-b428c971152d/7120_68.pdf?MOD=AJPERES) Accessed 26 August 2016

<sup>7</sup> EFSA Journal 2016;14(8):4546 <http://www.efsa.europa.eu/en/efsajournal/pub/4546> Accessed 26 August 2016

## **2 Summary of the findings**

### **2.1 Summary of issues raised in submissions**

No issues were raised in submissions as the submissions all supported the Application.

### **2.2 Risk assessment**

FSANZ's risk assessment is provided in SD1. In summary, evidence submitted in support of this Application provided adequate assurance that propionates fulfil the stated technological function as anti-microbial preservatives in processed meat, poultry and game products. Any additional dietary exposure to propionates resulting from their use as food additives in processed meat, poultry and game products presented no identifiable public health and safety concerns.

Propionic acid is a normal intermediary metabolite in humans and is naturally present in a wide variety of foods e.g. cheese and butter. Propionic acid and its sodium, calcium and potassium salts have a long history of use as food additives. Assessments by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and EFSA have concluded that there is no evidence of systemic toxicity resulting from oral exposure to propionates. Establishment of an acceptable dietary intake (ADI) expressed in numerical form was therefore not deemed necessary by JECFA and EFSA; FSANZ agreed with this statement.

In addition, propionates have been safely permitted as food additives in the Code for many years, in a range of food categories as detailed in the table to section S15—5.

A dietary exposure assessment was not conducted because of the lack of systemic toxicity resulting from oral exposure to propionates.

### **2.3 Risk management**

#### **2.3.1 Levels of addition**

This Application sought an extension to the existing use of propionates in food in Australia and New Zealand. In the absence of any public health or safety issues associated with this extended use identified by the risk assessment conducted by FSANZ, FSANZ recommends permitting the use of propionates (propionic acid (INS 280), sodium propionate (INS 281), potassium propionate (INS 282) and calcium propionate (INS 283) in processed meat, poultry and game products under conditions of GMP, as requested.

Specifically the permissions for propionates are to the following food categories in the table to section S15—5 as noted in the draft variation in Attachment A:

- 8.2 Processed meat, poultry and game products in whole cuts or pieces;
- 8.3 Processed comminuted meat, poultry and game products.

The use of propionates in processed meats, poultry and game at proposed levels to satisfy GMP is not expected to affect the taste of the products. Therefore their use in processed meat, poultry and game products is not expected to result in any change in consumption pattern.

#### **2.3.2 Specification**

As this Application is an extension of use of existing food additives which already have primary sources of specifications in section S3—2 (see SD1, section 2.5), no amendments to the specifications are necessary.

### **2.3.3 Analytical methods**

Analytical methods for identifying and quantifying propionates in foods and beverages, including processed meat, poultry and game products, already exist (see SD1, section 2.3).

### **2.3.4 Labelling**

Propionates when used as food additives must be declared in the list of ingredients on the label of most packaged foods in accordance with Standard 1.2.4 – Information requirements – statement of ingredients.

Subsection 1.2.4—7(1) provides that a substance used as a food additive must be listed in a statement of ingredients. This can occur in two ways:

- if the substance can be classified into a class of additives listed in Schedule 7:
  - the class name to be declared (e.g. ‘preservative’) as indicated in Schedule 7; and
  - followed in brackets by the name (propionic acid, sodium propionate, calcium propionate or potassium propionate) or code number (280, 281, 282 or 283 respectively) of the substance as indicated in Schedule 8; or
- Otherwise, the name of the substance (propionic acid, calcium propionate, sodium propionate or potassium propionate) as indicated in Schedule 8.

These labelling provisions will apply to the use of propionates in processed meat, poultry and game products, allowing consumers to identify whether propionates have been added.

There are some exemptions to these requirements that apply to food for sale that is not required to bear a label. These exemptions are set out in section 1.2.1—6 in Standard 1.2.1 – Requirements to have labels or otherwise provide information. The exemptions include a food that is made and packaged on the premises from which it is sold, or is packaged in the presence of the purchaser. Food sold in these situations does not have to bear a label and therefore any processed meat, poultry and game sold in this manner would not have to declare the presence of added propionates under Standard 1.2.4.

### **2.3.4 Impact analysis**

The Office of Best Practice Regulation (OBPR), in a letter dated 24 November 2010 (reference 12065), granted a standing exemption from the need for OBPR to assess if a Regulatory Impact Statement is required for the approval of applications relating to food additives.

This standing exemption was provided as such changes are considered as minor, machinery and deregulatory in nature, since the permission is voluntary and not mandatory. The exemption relates to the introduction of a food additive to the food supply that has been determined to be safe.

Notwithstanding the above exemption, FSANZ conducted a limited cost benefit analysis for this Application. That analysis found that extending the use of propionates as a food additive to processed meat products had benefits to the various sectors of the food industry. No costs to different stakeholders were identified that overrode these benefits. Nor was any benefit in rejecting the Application identified. As explained above, the extension of use of propionates as a food additive for processed meat products raised no public health and safety concerns.

FSANZ concluded that the direct and indirect benefits that would arise from a food regulatory measure developed or varied as a result of the Application outweighed the costs to the community, Government or industry that would arise from the development or variation of the food regulatory measure. Therefore, the preferred option was to prepare a draft variation to the Code to extend the use of propionates as food additives to processed meat products.

### **2.3.5 Risk management conclusion**

Based on the risk assessment conclusions, other than amending the Code to permit their extended use there are no additional risk management measures needed for the extension of use of propionates in processed meat, poultry and game under conditions of GMP.

## **3 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.

## **4 Risk communication**

### **4.1 Consultation**

Consultation is a key part of FSANZ's standards development process. After assessing the Application, public submissions were invited from 29 June to 10 August 2016, to obtain the views of interested parties on the impacts of the regulatory options. Five submissions were received; two from the food industry and three from government agencies. Late comments from a food industry organisation were also received. No issues were raised. All submitters supported the draft variation.

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

FSANZ applied a basic communication strategy to this Application, involving one call for submissions. The call for submissions was notified via the FSANZ 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.

The FSANZ Board's decision to approve the draft variations has been notified to the Australia and New Zealand Ministerial Forum on Food Regulation. 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 via email and the FSANZ website.

## **5 FSANZ Act assessment requirements**

### **5.1 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.

### **5.1.1 Cost benefit analysis**

As explained in section 2.3.4, 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.

### **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.

### **5.1.3 Any relevant New Zealand standards**

Schedule 15 applies in both Australia and New Zealand.

### **5.1.4 Any other relevant matters**

Other relevant matters are considered below.

## **5.2 Subsection 18(1)**

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

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

Propionates have been permitted as food additives in the Code for many years, in a range of food categories as detailed in Schedule 15. FSANZ had undertaken a risk assessment on the safety and efficacy associated with the requested extension of use (see SD1 and Section 2.2 above) and concluded that there are no public health and safety concerns from extending the use of propionates, as anti-microbial preservatives, in processed meat, poultry and game products under GMP conditions.

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

The variation to the Code does not vary the generic labelling requirements applicable to the use of propionates in processed meat, poultry and game products. The existing labelling requirements that apply to the use of propionates will also apply to this variation, and so will maintain the current level of information provided to consumers.

### **5.2.3 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.

## **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**

This Application was assessed using the best available scientific evidence. The Applicant submitted information on scientific studies and technical aspects 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 variation (food additive permission) makes the Australian and New Zealand regulations for the use of propionates in processed meat, poultry and game consistent with an international Codex standard (see Section 1.3.1).

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

The variation is voluntary and as such is not expected to affect the efficiency or competitiveness of Australia and New Zealand's food industry.

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

FSANZ did not identify any relevant issues relating to the promotion of fair trading in food for this Application.

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

The Policy Guideline 'Addition to Food of Substances other than Vitamins and Minerals'<sup>8</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 extending the use of propionates to processed meat, poultry and game products under GMP conditions, as anti-microbial preservatives, is consistent with these specific order policy principles.

## **Attachments**

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

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<sup>8</sup> <http://www.foodstandards.gov.au/code/fofr/fofrpolicy/pages/default.aspx>

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



### **Food Standards (Application A1113 – Extension of use of Propionates in Processed Meat) 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 variation 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**. 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 A1113 – Extension of use of Propionates in Processed Meat) 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 variations commence on the date of gazettal.

**Schedule**

**[1] Schedule 15** is varied by adding the following to both category 8.2 and category 8.3 in the table to section S15—5, in numerical order

280 281 282 283	Propionic acid and sodium and potassium and calcium propionates	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 A1113 which seeks to extend the use of propionates as anti-microbial preservatives in certain processed meat, poultry and game products. 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 purpose of this variation is to extend the permission for use of propionic acid and its calcium, potassium and sodium salts as anti-microbial preservatives to certain processed meat, game and poultry products under conditions of GMP. Permitting this extension of use of propionates to these products would provide manufacturers with an additional tool in the risk management of microbial activity, namely in the control of *Listeria monocytogenes*.

The variation will also provide consistency with a Codex international standard.

### **3. Documents incorporated by reference**

The variation does 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 A1113 included one round of public consultation following an assessment and the preparation of a draft variation and associated report. Submissions were called for on 29 June 2016 for a six-week consultation period.

A Regulation Impact Statement was not required because the proposed variations to section S15—5 are likely to have a minor impact on business and individuals.

## **5. Statement of compatibility with human rights**

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

## **6. Variation**

Item 1 amends Schedule 15 of the Code.

The amendment inserts permissions for each of the following food additives into both category 8.2 and category 8.3 in the table to section S15—5: propionic acid (INS 280), sodium propionate (INS 281), potassium propionate (INS 282) and calcium propionate (INS 283). The amendment sets the maximum permitted level for each additive at GMP (Good Manufacturing Practice).

The effect of this amendment is to permit the use of propionic acid and its calcium, sodium and potassium salts as food additives for any processed meat, poultry and game product falling within either category 8.2 or category 8.3, provided that the maximum level of the additive is consistent with GMP. This means the amount of additive used must be limited to the lowest possible level necessary to accomplish its desired effect.