FOOD STANDARDS Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

20 September 2018
[59-18]

Re-affirmation of variation **– Urgent Proposal P1046**

L-amino acid acetate in food for special medical purposes

Food Standards Australia New Zealand (FSANZ) has reaffirmed its decision to approve a draft variation to the Australia New Zealand Food Standards Code to permit the addition and use of L-arginine acetate in food for special medical purposes.

FSANZ had approved the draft variation on 14 September 2017. The draft variation was prepared and approved as part of Proposal P1046, which had been declared as an Urgent Proposal under section 95 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

The FSANZ Act required FSANZ to assess, and then call for public submissions on, the approved variation. FSANZ assessed the approved variation in accordance with section 99 of the FSANZ Act and then called for public submissions on 3 May 2018.

After considering all submissions received, FSANZ has decided to re-affirm its earlier decision to approve the variation. This report sets out the reasons for its decision to reaffirm the variation and is provided pursuant to section 101 of the FSANZ Act.

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Supporting document

The following document which informed the assessment of this Proposal are available on the FSANZ website:

Final consideration report – Urgent Proposal P1046

Executive summary

This Proposal was declared as urgent and prepared in response to a request from the New Zealand Ministry for Primary Industries (MPI) for urgent consideration of an amendment to the Australia New Zealand Food Standards Code (the Code) to permit the use of L-arginine acetate in food for special medical purposes (FSMP) to address a medical need. The request was made to remove an unintended negative impact on trade to enable FSMP containing L-arginine acetate to be imported.

FSANZ prepared and approved a draft variation to Schedule 29 of the Code to permit the use of L-arginine acetate in FSMP and a draft variation to Schedule 3 of the Code to provide an identity and purity specification for L-arginine acetate. The permission provided applies to all FSMP manufactured or imported into Australia and New Zealand. The approved variation was publically notified on 14 September 2017 and took effect on the date of the public notice.

The FSANZ Act required FSANZ to assess, and then call for public submissions on, the approved variation. FSANZ assessed the approved variation in accordance with section 99 of the FSANZ Act and then called for public submissions on 3 May 2018.

After considering all submissions received, FSANZ has decided to re-affirm its earlier decision to approve the variation.

1 Introduction

In August 2017, FSANZ received a request from the New Zealand Ministry for Primary Industries (MPI) for consideration of a variation to the Australia New Zealand Food Standards Code (the Code) to permit L-arginine acetate in food for special medical purposes (FSMP). The request was made to address a medical need and to remove an unintended negative impact on trade by enabling FSMP containing L-arginine acetate to be imported. The request was considered as an urgent proposal under sections 95 to 97 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

FSANZ assessed the proposal and then prepared a draft variation to Schedules 3 and 29 of the Code to approve the addition and use of L-arginine acetate in FSMP. In August 2017, FSANZ released a consultation paper seeking public submissions on the draft variation and on the option of approving the use of other relevant acetate forms of single L-amino acids in FSMP.

After considering the submissions received, FSANZ approved the draft variation, as prepared, which permitted the use of, and specification for, only L-arginine acetate in FSMP. The approved variation (the variation) was publically notified on 14 September 2017 and took effect on the date of the public notice and is at Attachment A.

The FSANZ Act required FSANZ to assess, and then call for public submissions on, the approved variation. FSANZ assessed the approved variation in accordance with section 99 of the FSANZ Act and called for public submissions on 3 May 2018. FSANZ also conducted a targeted consultation in February 2018 by approaching four major companies importing FSMP and two national organisations representing the food manufacturing industry in Australia and New Zealand.

1.1 The current standards and the variation

Standard 1.1.1 of the Code requires that a food for sale, such as a FSMP, must comply with the compositional, labelling, information, packaging and other requirements contained in the Code which apply to that food. Section 111—15 of that standard also provides that certain substances, when added to food in accordance with the Code, must comply with any relevant specifications set out in Schedule 3.

Standard 2.9.5 lists compositional, information, labelling and other requirements for FSMPs. Section 2.9.5—6 provides that a substance may be added to a FSMP if that substance is listed in the table to section S29—20 and is in the form specified in that table. The table to section S29—20 lists several L-amino acids including some L-amino acid compounds.

The variation amended the table to section S29—20 in Schedule 29 by inserting L-arginine acetate with the effect of permitting the addition of L-arginine acetate to FSMP products.

The variation also amended section S3—38 in Schedule 3 to provide an identity and purity specification for L-arginine acetate. The effect of the amendment was to limit addition to FMSP of L-arginine acetate sources to those that complied with that specification.

1.2 Reasons for assessing the variation

Sections 99 and 101 of the FSANZ Act requires FSANZ to assess the variation and then decide whether to: (a) re-affirm the decision to approve the variation; or (b) to prepare a proposal to develop a further variation (i.e. to repeal, amend or add to the variation). The Act

also requires FSANZ to call for public submissions after making its assessment, but before making that decision.

2 Summary of the assessment of the variation

FSANZ's assessment of the variation was detailed in the call for submissions issued by FSANZ on 3 May 2018. The call for submissions noted that:

- The variation provided for an alternative form of L-arginine to be used in FSMP manufactured in or imported into Australia and New Zealand.

- The risk assessment conducted by FSANZ before approving the variation concluded that use of L-arginine acetate in FSMP would not present a public health and safety concern. At the time of the call of submissions, FSANZ was unaware of any evidence to suggest that that assessment and that conclusion was incorrect.

- There are no relevant international standards for nutrient compounds in FSMP for the general population, only for infants and young children (CAC/GL 10–1979).

- FSANZ's assessment was that the variation would provide a potential net benefit, particularly for both industry and consumers who need or would benefit from FSMP containing this compound.

- The assessment also concluded there were no other measures that would be more cost effective than the variation. Variation of the Code was required to permit the addition and use of L-arginine acetate in FSMP.

Re-affirming the variation will support the continued importation of FSMP containing L-arginine acetate to assist those consumers who benefit from the L-arginine acetate in FSMP. As industry's use of this form of L-arginine is voluntary, this variation will continue to provide opportunities for product development and may expand markets.

2.1 Summary of issues raised

FSANZ conducted a targeted consultation in February 2018 by approaching four major companies importing FSMP and two national organisations representing the food manufacturing industry in Australia and New Zealand. Two responses were received which neither opposed the variation nor requested replacement or amendments to the variation.

FSANZ also publically consulted on a possible re-affirmation of the variation in May 2018 and particularly sought further information on whether costs had arisen from the variation that outweighed the direct and indirect community benefits.

A total of four submissions were received in support of the proposed re-affirmation of the draft variation to Schedules 3 and 29. No issues were raised in the submissions that indicated re-affirmation was not appropriate.

Table 1: Summary of comments and issues

Comment or issue	Raised by	FSANZ response
Support the affirmation of the approved variations. Do not support amending the variation to include other acetate forms of L-amino acids.	Government: NSW Food Authority, Vic Department of Health and Human Services, NZ Ministry for Primary Industries.	Noted.
Support the re-affirmation of the variation.	Industry: NZ Food and Grocery Council.	Noted.

2.2. Decision

FSANZ received no responses from stakeholders that suggested a need to revise or change FSANZ's assessment of the variation, including the risk assessment.

FSANZ did not receive any submissions suggesting that the costs associated with the variation outweighed its direct and indirect benefit. Nor did stakeholders identify any other measures as being more cost-effective than the measures contained in the variation.

FSANZ did not receive any submissions or responses from stakeholders calling for the variation to be amended to permit the use in FSMPs of acetate forms of other single L-amino acids or providing evidence for such an amendment.

Therefore, after having regard to all submissions received and to the other matters prescribed by the FSANZ Act (see below), FSANZ re-affirmed its decision to approve the variation made to Schedules 3 and 29 in September 2017.

2.3 Risk communication

2.3.1 Consultation

Consultation is a key part of FSANZ's standards development process. The process by which FSANZ considers standards matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views of interested parties on issues raised by the proposal and the impacts of regulatory options.

Public submissions were invited on the assessment of the variation which was released for public comment between 3 and 31 May 2018.

The call for submissions was notified via the Notification Circular, media release and through FSANZ's social media tools and the publication, Food Standards News. Subscribers and interested parties were also notified. Documents relating to the proposal, including submissions received, are available on the FSANZ website[1].

2.3.2 World Trade Organization (WTO)

There are no relevant international standards for nutrient compounds in FSMP other than for infants and young children. Re-affirming the variation to permit the use of L-arginine acetate in FSMP is unlikely to have a significant effect on international trade because these highly

[1] http://www.foodstandards.gov.au/code/proposals/Pages/P1046.aspx

specialised products comprise a very small segment of the market. Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Application of Sanitary and Phytosanitary Measures Agreement was not considered necessary.

2.4 FSANZ Act assessment requirements

2.4.1 Section 99

Section 99 of the Act required FSANZ to have regard to certain specific matters when assessing the variation. These considerations are summarised below.

a) whether the costs that have arisen, or will arise, from the variation outweigh the direct and indirect benefits to the community, government or industry that have arisen, or will arise, from the variation

No information was received through public submissions or targeted consultation that indicated costs have outweighed the benefit to the community, government or industry. Re-affirming the variation will allow for the continued importation of the FSMP containing L-arginine acetate.

b) whether other measures (available to the Authority or not) would be more cost-effective than the variation

No other measures were identified, whether available to FSANZ or not, that were more cost-effective than the variation.

c) all relevant New Zealand standards

Standard 2.9.5 and each of the schedules amended by the variation apply in New Zealand. There were no other relevant New Zealand standards that might be affected.

d) any other relevant matters, including FSANZ's statutory objectives in standards development

Other relevant matters are considered below.

2.4.2 Subsection 18(1)

In assessing the variation in 2017, FSANZ had regard to:

- the protection of public health and safety
- the provision of adequate information relating to food to enable consumers to make informed choices
- the prevention of misleading or deceptive conduct.

Before approving the variation, the acetate form of L-arginine was assessed as safe for consumers of FSMP. FSANZ is not aware of any reason to change that assessment. The Code's existing labelling provisions for FSMP meet the second and third objectives.

2.4.3 Subsection 18(2)

In assessing the variation in 2017, FSANZ has also had regard to:

- the need for standards to be based on risk analysis using the best available scientific evidence
- the desirability of an efficient and internationally competitive food industry
- the promotion of fair trading in food
- any written policy guidelines formulated by the Forum on Food Regulation.

FSANZ remains satisfied that the variation:

- was based on a risk assessment that used the best available scientific evidence
- removed a negative impact on trade that was not envisaged when Standard 2.9.5 was made
- is consistent with the Ministerial Policy Guideline on the Intent of Part 2.9 – Special Purpose Foods.

In terms of the promotion of fair trading in food and issues related to consumer information and safety, see sections 2, 2.4.1 and 2.4.2 above.

Attachments

A. Approved variation to the *Australia New Zealand Food Standards Code*
B. Explanatory Statement
C. Request from the New Zealand Government
D. Declaration of urgency

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

Food Standards (Proposal P1046 – L-amino acid acetate in Food for Special Medical Purposes) Variation

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The Board of Food Standards Australia New Zealand gives public notice of the approval of this variation under section 97 of the *Food Standards Australia New Zealand Act 1991*. The variation commences on the date specified in clause 3 of this variation.

11 September 2017

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

Note:

Public notice of the approval of the variation will be given in the *Food Standards Australia New Zealand Notification Circular* Number 24-17 published and issued on 14 September 2017. This means that this date is the date of public notice for the purposes of clause 3 of the variation.

1 Name

This instrument is the *Food Standards (Proposal P1046 – L-amino acid acetate in Food for Special Medical Purposes) Variation.*

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

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

3 Commencement

The variation commences on the date of public notice under subsection 97(4) of the *Food Standards Australia New Zealand Act 1991* of the approval of the variation.

Schedule

[1] Schedule 3 is varied by

[1.1] inserting in the table to subsection S3—2(2) in alphabetical order

L-arginine acetate	section S3—38

[1.2] inserting after section S3—37

S3—38 Specification for L-arginine acetate

For L-arginine acetate, the specifications are the following:

(a) full chemical name—(2S)-2-amino-5-(diaminomethylideneamino) pentanoic acid acetate;
(b) description—white crystalline powder;
(c) chemical formula—$C_8H_{18}N_4O_4$;
(d) CAS number—71173-62-1;
(e) purity (assay, on dried basis)—98.0-101.0%;
(f) loss on drying—maximum 0.5%;
(g) lead—maximum 0.4 mg/kg;
(h) arsenic—maximum 1 mg/kg;
(i) cadmium—maximum 0.2 mg/kg;
(j) mercury—maximum 0.4 mg/kg.

[2] Schedule 29 is varied by omitting from the table to section S29—20

L-arginine

substituting

L-arginine
L-arginine acetate

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 2 of Part 3 of the FSANZ Act specifies that the Authority may prepare a proposal for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering a proposal for the development or variation of food regulatory measures.

FSANZ prepared Proposal P1046 to permit the addition to Food for Special Medical Purposes of the acetate form of the single amino acids listed in section S29—20 of the Code.

Proposal P1046 was declared an Urgent Proposal for the purposes of Division 4 of Part 3 of the FSANZ Act.

The Authority considered the Proposal in accordance with sections 96 and 97 of the FSANZ Act and has approved a draft variation.

2. Purpose

The approved draft variation's purpose is to amend Schedule 3 to set a specification for L-arginine acetate and to amend Schedule 29 in order to permit the addition to FSMP of L-arginine acetate.

3. Documents incorporated by reference

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

4. Consultation

The Authority considered the Proposal in accordance with the procedure in Division 4 of Part 3 of the FSANZ Act. That consideration included one round of public consultation following an initial consideration and the preparation of a draft variation and associated assessment summary. After that public consultation, the Authority had regard to all submissions received and approved an amended version of the draft variation. The approved draft variation must be reviewed by the Authority within 12 months of its notification in accordance with Subdivision B of Division 4 of Part 3 of the FSANZ Act. Further public consultation is required as a part of that assessment.

A Regulation Impact Statement was not required because the approved draft variation is likely to have only 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] varies Schedule 3.

Item [1.1] varies the table to subsection S3—2(2). The variation amends that table to include in it references to 'L-arginine acetate' and to new section S3—38. The effect is that subsection 1.1.1—15(2) of Standard 1.1.1 will require L-arginine acetate, when added to food or sold for use in food, to comply with the specifications listed for L-arginine acetate in the new section.

Item [1.2] inserts new section S3—38 into Schedule 3. New section S3—38 provides the specifications for L-arginine acetate.

Item [2] amends Schedule 29. The item inserts a reference to L-arginine acetate into Column 2 of the table to section S29—20. Paragraph 2.9.5—6(1)(a) of the Code will provide that the effect of this amendment is to permit L-arginine acetate to be added to Food for Special Medical Purposes.

Attachment C – Request from the New Zealand Government

Ministry for Primary Industries
Manatū Ahu Matua

8 August 2017

Glen Neal
General Manager Food Standards
Food Standards Australia New Zealand
Lvl 3, 154 Featherston Street,
WELLINGTON 6011

Dear Glen

Request for FSANZ to vary Schedule 29

The Ministry for Primary Industries requests that FSANZ consider an urgent proposal to vary the Australia New Zealand Food Standards Code (the Code) to include the amino acid, L-arginine acetate, to S29—20 in Schedule 29. Schedule 29 lists substances that may be added to food for special medical purposes (FSMP), which are covered by Standard 2.9.5. L-arginine acetate is not currently a permitted form of amino acid as per section S29—20.

This request is due to the following reasons:

- a particular formulation of an FSMP that contains L-arginine acetate is required for a patient in New Zealand;
- the clinical dietitian treating the patient has confirmed to MPI in writing that this FSMP formulation containing L-arginine acetate is the patient's sole source of nutrition as the patient is unable to tolerate the current compliant formulation or any other similar FSMP available in New Zealand (i.e. formulations without L-arginine acetate);
- the manufacturer is unwilling to supply a non-compliant FSMP to New Zealand;
- the Pharmaceutical Management Agency in New Zealand (Pharmac) has given provisional approval to fund this particular FSMP for this patient, but is unable to give formal approval until the product can be legally supplied in New Zealand;
- MPI considers that there is no risk to public health and safety, and that it is in the public interest that this FSMP is permitted to be imported and sold in New Zealand;

MPI has considered options for allowing this FSMP to be imported to New Zealand, including discussions with officials at FSANZ. We are of the view that the most appropriate option to address this issue is to vary the Code to permit L-arginine acetate to be added to an FSMP.

There are limited options under the Food Act 2014 to provide an exemption from the Code. Annex D of the Agreement between the Government of Australia and the Government of New Zealand Concerning a Joint Food Standards System (the Food Treaty) provides for situations where different conditions in New Zealand or Australia necessitate a modification, separate standard or an opt-out of a standard. These different conditions must meet the threshold for being "prescribed grounds" (exceptional health, safety, third party trade, environmental or cultural grounds). We do not believe that New Zealand can meet the requirements for

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modification of Schedule 29 (Standard 2.9.5) or development of a *separate standard* as Standard 2.9.5 is no longer under development, and has already been adopted.

In the case of a New Zealand *opt-out*, the New Zealand Minister can inform the Council that New Zealand needs to opt out of a food standard. However, this can only occur in relation to a standard that is under development, or an approved food standard. We do not consider that a notification can occur once the approved food standard has been adopted (as the case is with Schedule 29 (Standard 2.9.5)).

Our concern is that it is only since the end of the transition period for Standard 2.9.5 that we have been made aware that this patient is only able tolerate the FSMP formulation with L-arginine acetate. Obviously this is a very serious health risk for this patient, and we ask that Schedule 29 be amended to include L-arginine acetate. Amending the Code in this way may also assist others in New Zealand or Australia who may have similar intolerances to the new formulation. Additionally, amending the Code preserves the integrity of a single standard covering both New Zealand and Australia.

We appreciate your consideration of this matter.

Jenny Reid
Manager, Food Science and Risk Assessment

Attachment D – Declaration of urgency

COMMONWEALTH OF AUSTRALIA

FOOD STANDARDS AUSTRALIA NEW ZEALAND

FOOD STANDARDS AUSTRALIA NEW ZEALAND ACT 1991

DECLARATION OF URGENCY

I, Glen Neal, an authorised Delegate for the purposes of section 95 of the Food Standards Australia New Zealand Act 1991 (the FSANZ Act), hereby declare under paragraph 95(2)(b) of the FSANZ Act that, in order to remove a negative impact on trade, **Proposal P1046 – L-Amino Acid Acetate in Food for Special Medical Purposes** is an urgent proposal for the purposes of Part 3, Division 4 of the FSANZ Act.

GLEN NEAL
GENERAL MANAGER
FOOD STANDARDS

15 August 2017