

3 May 2018

Call for submissions – Urgent Proposal P1046 – Assessment of the Variation

L-amino acid acetate in food for special medical purposes

On 14 September 2017, Food Standards Australia New Zealand (FSANZ) approved a variation to the Australia New Zealand Food Standards Code (the Code) after considering an Urgent Proposal to remove a negative effect on trade in by permitting L-arginine acetate in food for special medical purposes.

FSANZ has assessed the resulting variation and is calling for submissions to help FSANZ decide whether to re-affirm the variation or to prepare a proposal to replace, amend or add to the variation. For information about making a submission, visit the FSANZ website at [information for submitters](#).

All submissions on applications and proposals will be published on our website. We will not publish material that we accept as confidential, but will record that such information is held. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1991*. Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available on CD, rather than on the website. Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at [information for submitters](#).

Submissions should be made in writing; be marked clearly with the word ‘Submission’ and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website via the link on [documents for public comment](#). You can also email your submission directly to submissions@foodstandards.gov.au.

There is no need to send a hard copy of your submission if you have submitted it by email or via the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 31 May 2018

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters. Questions about making submissions or the application process can be sent to standards.management@foodstandards.gov.au. Hard copy submissions may be sent to one of the following addresses:

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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

On 14 September 2017, FSANZ approved a variation (the variation) to Schedules 3 and 29 of the Australia New Zealand Food Standards Code (the Code) to permit the use of L-arginine acetate in food for special medical purposes (FSMP). The variation was prepared and approved as part of an Urgent Proposal under Sub-Division A of Division 4, Part 3 of the *Food Standards Australia New Zealand Act 1991* (the Act).

The Act requires FSANZ to assess the variation and then decide whether to reaffirm the decision to approve the variation or to prepare a proposal to develop a further variation (i.e. to repeal, amend or add to the variation). The Act requires FSANZ to call for public submissions after making its assessment, but before making that decision.

FSANZ's risk assessment before approving the variation determined that use of L-arginine acetate in FSMP would not present a public health and safety concern. FSANZ has assessed the variation by giving regard to all relevant matters including whether the costs that have arisen, or will arise; from the variation outweigh the direct and indirect benefits to the community, government or industry. At this time and following a targeted consultation with the industry, FSANZ's assessment is that no other measures have been identified as more cost-effective, nor has FSANZ identified any issues that warrant amending the variation or the preparation of a separate proposal.

Re-affirming the variation will continue to support the importation of FSMP containing L-arginine acetate and will provide for consumers who would benefit from L-arginine acetate in FSMP. As the use of L-arginine acetate is voluntary, this option will continue to provide opportunities for product development and may expand markets. There are no costs identified with re-affirming the variation. FSANZ's assessment is that re-affirmation would continue the net community benefit determined at approval in September 2017.

FSANZ now calls for submissions to assist FSANZ decide whether to re-affirm the variation to Schedules 3 and 29, available in Attachment 1, or to prepare a proposal to replace, amend or add to the variation. Questions to submitters are collated in Attachment 2 – Summary of questions to submitters.

1 Introduction

1.1 The Variation

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 remove an unintended negative impact on trade by enabling FSMP containing L-arginine acetate to be locally available to address a medical need. The request was considered as an urgent proposal under sections 95 to 97 of the FSANZ Act.

A call for submissions proposing to approve the use of L-arginine acetate and possibly other relevant acetate forms of single L-amino acids in FSMP was released in August 2017. All submissions supported the approval of L-arginine acetate and extending the permission to other single L-amino acid acetates. However, one submission did not support the extension under the declared urgent considerations. The submissions are available on FSANZ [website](#). The Board approved the [Final consideration report](#) which permitted the use of, and specification for, only L-arginine acetate in FSMP on 13 September 2017. The approved variation (the variation) took effect on 14 in September 2017 and is at Attachment 1.

1.2 The current standards and the variation

Standard 1.1.1 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 of that standard 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 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 to provide a specification for L-arginine acetate. The effect of the amendment was to limit addition to FSMP of L-arginine acetate sources to those that complied with that specification.

1.3 Reasons for assessing the variation

The Act requires FSANZ to assess the variation and then decide whether to reaffirm the decision to approve the variation or 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 was required to assess the variation with a view to deciding whether the variation should be re-affirmed, repealed or other amendments made to the Code. In making that

assessment, section 99 of the FSANZ Act required FSANZ to have regard to certain matters. FSANZ's consideration of these matters is summarised below

A regulation impact statement was not required for approval as FSANZ has an exemption from the Office of Best Practice Regulation when changes are voluntary, deregulatory and do not have a significant impact on business or individuals (reference 14943).

The variation provided for an alternative form of L-arginine to be used in FSMP manufactured in or imported into Australia and New Zealand. FSANZ's risk assessment determined that use of L-arginine acetate in FSMP would not present a public health and safety concern. FSANZ also noted that 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). Therefore, approving the variation in 2017 provided a potential net benefit for both industry and consumers who need or would benefit from FSMP containing this compound.

However, subsection 99(2)(a) of the FSANZ Act requires FSANZ to have regard to whether costs that have arisen, or will arise, from the variation outweigh the direct and indirect benefits to consumers, government or industry. The costs and benefits of the regulatory options were considered when approving the variation. This was not intended to be an exhaustive, quantitative economic analysis of the options and, in fact, most of the effects that were considered cannot be assigned a dollar value. Rather, the assessment sought to highlight the qualitative effects of criteria that were relevant to each option.

Since approving the variation, 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 has not received additional information that would influence this assessment of likely costs and benefits arising from the variation. FSANZ now calls for submissions to assist FSANZ decide whether to re-affirm the variation or to prepare a proposal to replace or amend the variation.

Reaffirming 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 option would continue to provide opportunities for product development and may expand markets. There are no costs identified with re-affirming the variation. FSANZ's assessment is that reaffirmation would continue the net community benefit determined at approval in 2017.

Question to submitters:

1. Do you agree that the variation to Schedules 3 and 29 on the use of, and specification for, L-arginine acetate in FSMP should be re-affirmed? Please state your reasons.
2. If not, what further variation is should be made to Schedule 29 permitting the use of L-arginine acetate in FSMP?
 - a. Describe any potential benefits associated with varying Schedule 29
 - b. Describe any potential costs associated with varying Schedule 29.
3. If not, what further variation should be made to the specification of L-arginine acetate in Schedule 3?
 - a. Describe any potential benefits associated with varying Schedule 3
 - b. Describe any potential costs associated with varying Schedule 3.

2.3 Risk communication

2.3.1 Consultation

Consultation is a key part of FSANZ's standards development process. FSANZ acknowledges the time taken by individuals and organisations to make submissions on this urgent Proposal. Every submission on this proposal will be considered by the FSANZ Board. All comments were valued and contribute to the rigour of our assessment.

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 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 requires FSANZ to have regard to certain specific matters when assessing the variation. These matters are considered 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**

Re-affirming the variation will allow for the continued importation of the FSMP containing L-arginine acetate. FSANZ has not received submissions before the approval or during the subsequent targeted consultation to expand the permission to acetate forms of other single L-amino acids. FSANZ has also not received submissions in the process to date that suggest a feasible alternative to re-affirming the variation.

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

No other measures have been identified as yet, whether available to FSANZ or not, that may be more cost-effective than the variation. However, this will be further evaluated if submissions propose a feasible alternative to the status quo of re-affirming 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, FSANZ has 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.

In this regard, FSANZ noted the following:

Prior to approval of 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, 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.

In this regard, FSANZ noted the following:

The variation was based on a risk assessment of appropriate scientific evidence. It removed the current negative impact on trade that was not envisaged when Standard 2.9.5 was made. Also, the variation is consistent with the *Ministerial Policy Guideline on the Intent of Part 2.9 – Special Purpose Foods*.

Attachments

1. Approved variation to the Australia New Zealand Food Standards Code (2017)
2. Summary of questions to submitters

Attachment 1 – 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

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 2 – Summary of questions to submitters

Question to submitters:

1. Do you agree that the variation to Schedules 3 and 29 on the use of, and specification for, L-arginine acetate in FSMP should be re-affirmed? Please state your reasons.
2. If not, what further variation is should be made to Schedule 29 permitting the use of L-arginine acetate in FSMP?
 - a. Describe any potential benefits associated with varying Schedule 29
 - b. Describe any potential costs associated with varying Schedule 29.
3. If not, what further variation should be made to the specification of L-arginine acetate in Schedule 3?
 - a. Describe any potential benefits associated with varying Schedule 3
 - b. Describe any potential costs associated with varying Schedule 3.