Comments from the Victorian Departments of Health and Human Services and Economic Development, Jobs, Transport and Resources

Due date of submission – 31 May 2018

The Victorian Departments of Health and Human Services and Economic Development, Jobs, Transport and Resources (the departments) welcome the opportunity to provide comments on Urgent Proposal P1046 – Assessment of the Variation.

The use of L-arginine acetate was approved by FSANZ on 14 September 2017 under Urgent Proposal P1046 – L-amino acid acetate in food for special medical purposes (the proposal). As required by the *Food Standards Australia New Zealand Act 1991*, Urgent Proposal P1046 – Assessment of the Variation (the variation) seeks to assess the variation and decide whether to reaffirm, repeal, amend or add to the variation.

The risk assessment in the proposal final consideration report concluded that permission for acetates of single L-amino acids for use in food for special medical purposes (FSMP) would not present a public health or safety concern.

1. **Do you agree that the variation to Schedule 3 and 29 on the use of, and specification for, L-arginine acetate in FSMP should be re-affirmed? Please state your reasons.**

The departments **support reaffirming the variation** on the basis that no health or safety concerns were identified in the risk assessment. This decision would also enable individuals currently using FSMP that contain L-arginine acetate to continue accessing their preferred product.

The departments recognise that amending the variation to extend permission to all acetate forms of L-amino acids could reduce regulatory burden for potential future product innovations. However, we **do not currently support amending the variation** to include all acetate forms of L-amino acids for the following reasons:

- A market for all acetate forms of L-amino acids in FSMP has not been established. The vast majority of FSMP are imported into Australia and New Zealand from Europe, where acetate forms of L-amino acids are not permitted for use in FSMP except for L-arginine acetate which is already permitted for use in FSMP in Australia. Product innovations containing alternative acetate forms of L-amino acids would require safety assessment by the European Food Safety Authority (EFSA). This would provide sufficient notice to enable an application to vary the Australia New Zealand Food Standards Code (the code), while also ensuring an adequate and targeted risk assessment of the application.
- The risk assessment has not adequately considered the wide range of FSMP users and the implications of potentially having all amino acids present in the acetate form. FSANZ indicated there are no health or safety risks associated with the use of acetate forms of all single L-amino acids in FSMP. However, there has been little consideration given to the cumulative effect of multiple acetate forms of amino acids being used in a single FSMP and the implications for those with altered metabolic or reduced excretory functions. FSMP are administered to a range of vulnerable individuals with a variety of health conditions including but not limited to: kidney

failure, liver disease, chronic obstructive pulmonary disease, cancer and post-operative patients. Careful consideration needs to be given to the potential risks associated with any compositional change to FSMP due to the variable physiological capacity of this highly heterogeneous population.

- Extending the permissions to all acetate forms of amino acids will require significant additional work for unclear benefit for potential product innovations. The identity and purity specifications are not available for many acetate forms of amino acids in the sources listed in Schedule 3 – Identity and purity, and additional work would be required to set specifications for the many acetate forms of amino acids. It would be more practical to assess and set specifications as required as part of the FSANZ application process rather than to approve and develop specifications for all acetate forms of amino acids.

2. If not, what further variation should be made to Schedule 29 permitting the use of L-arginine acetate in FSMP?

a. Describe any potential benefit associated with varying Schedule 29

b. Describe any potential cost associated with varying Schedule 29

The departments do not have any suggestion for variation to 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 benefit associated with varying Schedule 29

b. Describe any potential cost associated with varying Schedule 29

The departments do not have any suggestion for variation to Schedule 3.