

Comments from the Victorian Department of Health and the Victorian Department of Energy, Environment and Climate Action.

Due date of submission – 20 December 2023

The Victorian Departments of Health and Energy, Environment and Climate Action (the departments) welcome the opportunity to respond to this application to amend the Australia New Zealand Food Standards Code (the Code).

Application A1247 D-allulose as a novel food seeks to permit the sale of the low energy sugar substitute, D-allulose as a novel food, and the enzyme used to produce D-allulose, D-psicose 3-epimerase, as a processing aid.

The departments recognise that permission for D-allulose and D-psicose 3-epimerase would provide an additional sugar substitute which could provide benefits for industry through product innovation, and consumers through an increased variety of reduced energy foods. While the departments support permissions for D-allulose and D-psicose 3-epimerase in principle, we have identified some potential safety and consumer information matters that require further consideration. These are discussed in further detail below.

Labelling of foods containing D-allulose

The departments consider the proposed requirements to exclude D-allulose from sugars declared in the nutrition information panel (NIP), and to permit foods containing D-allulose to make nutrition content claims about sugars (including 'no added sugar' and % free) does not support consumers to make informed food choices because D-allulose is a monosaccharide and falls within the definition of sugar under section 1.1.2-2 of the Food Standards Code. While the energy content of D-allulose (2 kJ/g) is lower than the only other low energy sugar currently permitted in the Code, D-tagatose (11 kJ/g), the departments are concerned that establishing labelling requirements based on the significance of energy content is ambiguous and will create uncertainty as further low energy sugars are developed and commercialised. For regulatory simplicity and certainty, the departments' preferred approach is that, like D-tagatose, D-allulose is not exempt from labelling requirements and restrictions for mono- and disaccharides, including labelling sugars in the NIP and sugar nutrient content claim permissions.

The departments also suggest there should be consideration of the need for a mandatory advisory statement under section 1.2.3 – 2 related to the risk of a laxative effect because D-allulose is only partially absorbed from the gastrointestinal tract, and there is evidence that this creates an osmotic laxative effect at moderate intake levels. While the proposed maximum permitted levels for D-allulose are below the level that would require the mandatory labelling under section 1.2.3 – 2 for most foods, there are a small number of categories that pose a risk for laxative effect due to higher permitted levels (chewing gum, sugar substitutes). It is also possible that D-allulose may be used in foods with other sugar replacers that are also only partially absorbed from the gastrointestinal tract, and that the combined usage may trigger the mandatory labelling requirement.

Microbiological safety of D-allulose

FSANZ's safety assessment only included studies of D-allulose consumption in healthy adults as a result of study exclusion criteria which consistently removed participants with diabetes, hepatic and renal function disorders, pregnancy or were lactating. The

departments are concerned about the lack of data to establish microbiological safety in these subpopulations, particularly in individuals with renal conditions given it has been demonstrated that a high proportion of D-allulose is passed through and excreted via the kidneys, and in diabetic populations as they may be large consumers of foods containing low energy sugar substitutes. The departments also note that while several microorganisms were identified as carrying D-allulose metabolism genes (and therefore presenting potential risk for bacterial urinary tract infection), the clinical studies included in the safety assessment only considered *K. pneumoniae*.

The departments suggest further consideration of microbiological risks and mitigation, including across uro-pathogenic bacteria and in potentially vulnerable consumer subpopulations is required to establish safety.

Submitted to Application A1247 D-allulose as a Novel Food
Submitted on 2023-12-20 11:13:27

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Introduction

Name

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[Redacted] of your business, organisation (please write N/A if this does not apply)

Organisation:
Department of Health Victoria

Please identify which of the following groups you mostly closely identify with

Groups to which you belong:
Government

If other please specify:

Who is the contact person for this submission

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Submission

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