



**MANILDRA GROUP**

**100% AUSTRALIAN OWNED**

## **SUBMISSION**

**Application A1230**

**Very Low Energy Diets (VLED)**

**December 2021**

**DETAILS**

[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
	[REDACTED]
	[REDACTED]
	[REDACTED]
[REDACTED]	
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
	[REDACTED]

**Commercial in Confidence**

Manildra has information to support this submission which is commercial in confidence. This information will be provided in a separate document.

## INTRODUCTION

The Manildra Group (Manildra) makes this submission in response to the Food Standards Australia New Zealand (FSANZ) call for submissions on Very Low Energy Diets (VLED) (A1230, 19 November 2021, 180-21).

Manildra is an Australian operation whose core business is the processing of wheat into a wide range of wheat derivatives from sparingly refined to highly refined and modified. A large volume of many different products is manufactured for Australian and international food applications.

In accordance with its ISO9000 and ISO14000 status and through its Commitment to Excellence, the Manildra Group complies with national and international food regulations and endeavours to provide **all** consumers and customers with materials and ingredients to meet their needs and enhance their enterprises.

Manildra endorses FSANZ's primary objectives "to protect the health and safety of individuals" and "to ensure that consumers are provided with adequate information to make appropriate food choices".

## Overall Position

Manildra notes the purpose of this consultation is to seek feedback on a proposed amendment to regulate Very Low Energy Diets (VLED) currently in the Australian and New Zealand (ANZ) market in alignment with the *CODEX Standard for Formula Foods for Use in Very Low Energy Diets for Weight Reduction* (Codex STAN 203-1995).

Manildra broadly **supports** the following proposed amendments:

- adding definitions for *very low energy diet* and for *very low energy food* to the Code
- removing the exclusion of foods formulated and represented as being for the dietary management of obesity or overweight from being FSMP
- setting requirement to ensure VLED are consumed within the recommended daily quantity when used as the sole source of nutrition
- including a new division to set compositional requirements for very low energy diets, and
- including a provision stating that Standard 2.9.6 will cease to apply to VLED two years after commencement of the draft variation.

Manildra **does not support** the proposed requirement for protein with a nutritional quality equivalent to a protein digestibility corrected amino acid score (PDCAAS) of 1 as this impacts on the use of plant proteins, including wheat in VLEDs. We note that the Applicant has not requested to align with Codex STAN 203-1995 protein quality prescription and suggests that specifying protein quality is unnecessary for VLED.

**Manildra request the requirement for a PDCAAS score of 1 is NOT included in the proposed drafting for Division 5 of Standard 2.9.5 – Very Low Energy Diets – proposed nutrient criteria.**

## MANILDRA GROUP BUSINESS

### Manildra – VLED product

Manildra currently supply a functional ingredient (GEMPRO HiQ) into the VLED market in the form of a quality protein hydrolysate made from wheat. It is a highly soluble, glutamine rich protein with minimal flavour.

The Product Data Sheet (PDS) for this product is provided as **Appendix 1**.

[REDACTED]

Information on the PDCAAS for GEMPRO HiQ is set out in **Appendix 1**. (Please note: the PDCAAS information is confidential)

This wheat protein hydrolysate has been used in VLED products sold in the Australian market for 15 years without the requirement for a PDCAAS score of 1.

### History of development

Manildra commenced research into a fully soluble wheat protein in 2003 and started commercially manufacturing wheat protein hydrolysate in 2005. This was initially manufactured through a contract manufacturer as the business developed. Since 2005 Manildra has significantly invested in continued development of these products.

### New Plant

In 2019 in response to an increased request to supply the wheat protein hydrolysate, Manildra designed and commissioned a plant at its principal wet manufacturing site to enable the product to be made in Australia from all Australian ingredients.

Manildra has placed significant amount of investment into this new plant.

Additional information to support this submission is provided in confidence in a separate document.

**SPECIFIC COMMENTS**

This section of the submission specifically addresses Manildra's request for the requirement for a PDCAAS score of 1 to be reviewed to include an additional score for wheat protein to enable its continued use in these products in the proposed drafting for Division 5 of Standard 2.9.5 – Very Low Energy Diets.

In this section Manildra will present information supporting our position.

Manildra believes that the inclusion of a PDCAAS score of 1.0 is not required for the following reasons:

1. Nutrition Status of wheat protein
2. Cost impact to the business
3. Applicant has not requested the inclusion of a PQ method

Manildra also note that there are there are several methods for determining protein quality (PQ) for human food, with varying advantages and disadvantages. This is further discussed in our submission.

**Nutrition Status of Wheat Protein (& other plant proteins)**Wheat protein - nutrition profile

In 2021 8,000,000 mt of wheat was consumed in Australia. This has steadily increased over the last 30 years from 4,000,000 mt.

Wheat, and its constituents, are formulated into various products such as bakery, tortilla, pizza, noodle, crackers, snacks, breakfast cereals, pasta, sauces/gravy, batters and breading's and textured meat.

Wheat protein is used in its unmodified and modified form to create products that provide unique characteristics to cater for diets such as high protein/low carbohydrate, Low FODMAP, Keto and for egg replacement.

Manildra has been manufacturing a wheat protein hydrolysate for use in VLED since 2005. [REDACTED]

[REDACTED]. Since its introduction to our range, we have received no requests from dietitians, customers, or consumers regarding the amino acid profile nor any suggestion that our product is inferior in any way to other protein sources in this food application.

We note that high quality proteins are defined as a protein with a PDCAAS of 1.0, which includes common proteins such as casein, egg, milk, whey, and soy (EFSA 2015, WHO/FAO/UNU 2007, Sarwar 1997).

Wheat protein contains the essential amino acids set out in the Report of the Joint FAO/WHO Expert Consultation on Protein Quality Evaluation, Bethesda, MD USA, 4-8 December 1989, FAO Food and Nutrition Paper No. 51, Food and Agriculture

Organisation of the United Nations, Rome, 1991 however due to the low level of lysine, the PDCAAS does not meet the required score of 1 (based on adult values).

We note the method requires the use of values for 2–5-year children rather than adult values which would be more appropriate given the target market for these products.

Further, we refer to a study completed by Marney et al (2018) which studied the use of [REDACTED] in VLCD in cardiac surgery patients with obesity and metabolic syndrome which showed that this product was well tolerated and resulted in a significant weight loss as well as reductions in waist circumference, cholesterol and triglycerides and present this as further evidence that wheat protein hydrolysate is fit for purpose in VLEDs without the requirement for a PDCAAS score of 1.0.

Wheat protein (or plant proteins more generally) should not, by default, be set up as not high quality based on a test that is specifically designed for products that service a very niche market VLED.

#### Other plant proteins

An often-neglected aspect of plant proteins is their high content of some important dispensable/conditionally indispensable amino acids. The PDCAAS method of evaluating protein quality focuses only on indispensable amino acids and generally on whole body protein requirements.

However, since the development of the PDCAAS concept, the knowledge base around the health or performance-related effects of individual amino acids, both indispensable and conditionally indispensable has grown dramatically. For example, whey protein has received much attention for muscle building due to its high level of leucine, which serves as a nutrient signal for initiating the process of muscle protein synthesis. However, it is important not to forget the vital physiologic functions of dispensable/conditionally indispensable amino acids found in large amounts in plant proteins. Soy protein, while not as high as whey in leucine, is nearly three times higher in arginine, 2–3 times higher in glutamine, and has double the glycine content.

Other plant proteins can be high in these amino acids as well. Arginine is necessary for the body's synthesis of nitric oxide (vasodilator) and creatine, for urea cycle function, for regulating hormone secretion, and for immune function. Glutamine is a primary fuel source for rapidly proliferating cells such as those in the immune system and gastrointestinal tract and functions in the synthesis of arginine, ornithine, and several other compounds. Glycine is critical for collagen synthesis, comprising up to 1/3 of the amino acids in collagen and some studies suggest that its biosynthesis in humans may not be adequate to meet requirements. Although amino acids such as arginine, glutamine, and glycine might not be classified all the time as indispensable amino acids, they perform many critical functions and plant proteins can be significant sources.

Thus, the content of these dispensable/conditionally indispensable amino acids deserves to be taken into consideration when evaluating the value of plant proteins in the diet.

#### Current products on the market and protein quality

Currently on the market in Australia there are a variety of VLEDs that use different protein sources including whey protein isolate (containing soy lecithin), whey protein concentrate, milk solids, milk protein (primarily casein and lactalbumin), wheat protein, soy protein isolate, pea protein, hemp seed protein, brown rice protein and hydrolysed collagen. Manildra has been supplying GEMPRO HiQ to manufacturers of these products for 15 years with no requirement to meet a PDCAAS of 1.

We also note that the applicant has not requested to align with Codex STAN 203-1995 protein quality prescription and suggests that specifying protein quality is unnecessary for VLED. Further, FSANZ has noted that:

*“FSANZ assumes that most VLED on the ANZ market have a PCDAAS of 1.0. Where products do not meet this quality, it is assumed that consumption of a variety of VLED across the individuals daily intake would manage any risks associated with protein quality and nutritional adequacy.”<sup>1</sup>*

Ensuring a range of VLED products in the market is important and FSANZ have recognised that VLED cereal bars are currently available. Requiring a PDCAAS of 1 for the base ingredients of these products will impact on the cost to manufacture and supply. This is addressed under a later section of this submission.

Proteins and amino acids play an integral role in weight loss and are necessary for inclusion in VLED products. A PDCAAS is based on amino acids that are considered essential or indispensable as they cannot be synthesised fast enough by the human body to supply its demand, these are phenylalanine, valine, threonine, tryptophan, methionine, leucine, isoleucine, lysine, and histidine.

Moreover, only certain amino acids are considered important to achieve the objective of a VLED diet. These amino acids enhance weight loss effects far above those of other amino acids, these include Methionine, Arginine and Glutamine. Wheat protein hydrolysates have these amino acids and are limited in the PDCAAS by a low level of Lysine which is not considered essential in VLED (Geidenstam et al, 2017; Laviano et al, 2014; Abboud et al, 2019)

Manildra is concerned that the requirement for a PDCAAS score of 1.0 will set a precedent for wheat protein as not being of ‘high quality’ based on a test protocol that is specifically designed for the niche VLED market.

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<sup>1</sup> SD1 A1230, p14

## Food allergens

In Australia and New Zealand, the foods or food groups that cause about 90% of all allergic reaction are identified as: peanuts; specific named tree nuts: almond, Brazil nut, cashew, hazelnut, macadamia, pecan, pine nut, pistachio, and walnut; soy; milk; egg; wheat; fish (finfish); crustaceans; molluscs; sesame; and lupin.<sup>2</sup>

It is important to consumers who require VLED to have access to a range of products based on different protein sources to cater for the food allergic consumer. Those with a dairy allergy will need access to alternative VLED products using an alternative protein source.

Again, the requirement for a PDCAAS score of 1.0 for wheat (and plant) proteins may have an unintended consequence of increasing the cost of cereal based VLED products. This is addressed under a later section of this submission.

The Report of the Joint FAO/WHO Expert Consultation (1989) noted that:

*The low protein quality of a vegetable protein source can be improved by the addition of supplementary protein or the limiting amino acid, and by protein complementation. The addition of amino acids to increase protein quality of a protein source should only be considered when protein supplementation or complementation have proved impracticable (125) since benefits from the addition of amino acids have not been demonstrated consistently in humans (126). Furthermore, an excess of a supplementary amino acid such as synthetic methionine may have a deleterious effect on infants and children (125).<sup>3</sup>*

## Other considerations

Several of the proteins used in VLED are thought to originate from GMO sources, wheat protein hydrolysate is produced from GMO free wheat and with no GMO processing aids or ingredients, this offers the consumer a choice in respect to GMO and is an important consideration when determining a VLED to purchase.

## **Cost Impact to Business**

We note that consideration of the costs and benefits in the *Call for Submissions* paper prepared by FSANZ is not intended to be an exhaustive, quantitative economic analysis of the proposed measures. Rather, the assessment sought to highlight the likely positives and negatives of moving away from the status quo by codifying VLED within Standard 2.9.5 - FSMP.

Manildra further note FSANZ's view that it is also unlikely that compliance to the new regulation will generate additional costs as evidence suggests products on the ANZ market are currently compliant with FSMP requirements and Codex STAN 203-1995, which the proposed regulations align with.

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<sup>2</sup> <https://allergenbureau.net/food-allergens/>, accessed 16/12/2021

<sup>3</sup> FAO/WHO report, page 40



FSANZ have noted that the proposed changes may result in a greater availability of VLED, increasing competition and reducing the cost to consumers.

Manildra wish to provide data on the cost to the business to comply with the proposed requirement to meet a PDCAAS of 1. These costs will increase the cost of VLED based on wheat (and plant) based proteins due to the requirement to supplement with lysine as discussed below. Alternatively, manufacturers may choose to move away from wheat-based ingredients, potentially limiting the choice available to those seeking VLED.

#### Costing case study

The costs involved to produce a wheat protein compliant with the proposed PDCAAS score of 1 include:

1. Cost of EAA
2. Cost of addition of the EAA
3. Cost of plant upgrade OR outsourcing to a contract blender
4. Cost of testing for compliance to the PDCAAS score

Detailed costing information to support this submission is provided in confidence in a separate document.

#### **Applicant has not requested a PQ measure**

We refer to page 2 of the executive summary published by FSANZ in relation to this “The applicant has not requested to align with Codex STAN 203-1995 protein quality prescription and suggests that specifying protein quality is unnecessary for VLED.”

Manildra would agree with this statement and acknowledges this further adds weight to the removal of this from the proposed standard.

We refer to page 4 of the application submitted by the applicant and note the section 1.3.2.2 European Union (EU) stating that the adoption of the EU measures would require significant reformulation of products currently on the ANZ market and highlight that if the PDCAAS score is adopted from the Codex STAN 203-1995 this would also require many suppliers currently in the market to reformulate, sometimes at a significant cost (including ingredients and changes to labelling).

#### **Methods for determining Protein Quality (PQ)**

Manildra also note that there are several methods for determining protein quality (PQ) for human food, with varying advantages and disadvantages. In the report of Joint FAO/WHO Expert Consultation (1989) - FAO have recommended further research needs to be carried out.<sup>4</sup>

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<sup>4</sup> Summary of Conclusions and Recommendations, p 43, FAO Protein Quality Evaluation

In a subsequent report – Dietary protein quality evaluation in human nutrition (FAO, 2013) included the following key finding:

*A new protein quality measure (digestible indispensable amino acid score; DIAAS) is recommended to replace PDCAAS. DIAAS is defined as:  $\text{DIAAS \%} = 100 \times [(\text{mg of digestible dietary indispensable amino acid in 1 g of the dietary protein}) / (\text{mg of the same dietary indispensable amino acid in 1g of the reference protein})]$ .*

A recent review on *Comparison of methodologies used to define the protein quality of human foods and support regulatory claims* by Mansilla et al (2020) provides a comprehensive look into the methodologies for determining PQ of foods. There are a number of options available and these need to be considered together with their advantages and disadvantages, the food products and the target population.

## **Conclusion**

Manildra thanks FSANZ for the opportunity to provide feedback on the consultation for A1230.

Manildra is ready to engage with FSANZ further to ensure that a final decision on this consultation does not disadvantage wheat/plant proteins which are currently a valuable source of protein for VLED products.

The potential to devalue the contribution that wheat and other plant products made to the nutritional quality of the food supply and VLED products must be considered to ensure unintended consequences are fully considered.

**Manildra request the requirement for a PDCAAS score of 1 is NOT included in the proposed drafting for Division 5 of Standard 2.9.5 – Very Low Energy Diets – proposed nutrient criteria.**

## References

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