
**Australasian Society of Inborn Errors of Metabolism
Dietitians Group**

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Corner Hawkesbury Road
and Hainsworth Street
Locked Bag 4001
Westmead NSW 2145
Sydney Australia
DX 8213 Parramatta
Tel +61 2 9845 0000
Fax +61 2 9845 3489
www.chw.edu.au
ABN 53 188 579 090

SUBMISSION REGARDING P242 FOODS FOR SPECIAL MEDICAL PURPOSES (FSMP)

The Dietitian members of the Australasian Society for Inborn Errors of Metabolism appreciates the opportunity to comment on the abovementioned Proposal as FSMP are important products used by dietitians as a treatment modality for specific clinical conditions. It is essential that such a standard ensures the continued availability of these foods at a reasonable price.

In particular we are concerned at the potential impact on the availability of FSMP in Australia for our patients with inborn errors of metabolism. These are relatively rare conditions and there are no local manufacturers of product, which are currently sourced from USA or Europe. Such products are essential in the medical management of these conditions and a variety aids compliance. There are potentially serious medical consequences if such products became unavailable, and increased costs if manufacturers have to re-formulate and produce different labels. Given the labelling requirements set out in P242 it would seem that manufactures would need to implement a number of changes to current labels in order that FSMPs comply. This would appear to be rather onerous on manufacturers given current labels comply with either EU (European Union) or American labelling requirements.

We agree with the Dietitians Association of Australia that there is a problem with the maximum levels of nutrients being expressed as a proportion of energy when energy is not one of the nutrients being supplemented as per Table 2 of the Appendix. An example of this is the amino acid, vitamin, mineral and trace element supplements used for children and adults with PKU. These supplements replace the nutrients usually found in higher protein foods. To make the diet as palatable and varied as possible, the energy level of the supplement is relatively low. This allows the individual to meet their energy needs from low protein foods. Therefore 'maximum permitted' nutrient levels cannot meaningfully be expressed on an energy basis to cover these types of FSMP.

The table below from the DAA submission highlights this problem where maximum levels proposed in the draft standard are exceeded by the protein supplements used by sufferers of PKU.

/ 100KJ	Max Amount	XP Maxamaid (Nutricia/SHS)	XP Maxamum (Nutricia/SHS)	Phenex 2 (Abbott)
Vitamin A mcg	34	40	34.77	38.28
Thiamin mg	0.12	0.11	0.06	0.23
Niacin mg	0.4	2.22	1.63	1.84
Folate mcg	11.5	38	6.1	26.68
Vitamin B12 mcg	0.17	0.27	0.08	0.56
Vitamin D mcg	0.57	0.912	0.85	0.57
Biotin mcg	1.8	9.12	2.14	7.54
Pantothenic Acid mg	0.35	0.28	0.23	0.81
Calcium mg	28.7	61.56	35.38	51
Magnesium mg	4	15.2	10	13.05
Iron mg	0.5	0.91	0.86	0.75
Phosphorus mg	46	61.56	29.28	51.04
Zinc mg	0.46	0.99	0.61	0.75
Copper mcg	114	140	60	60
Chloride mg	42	34.2	35.67	54.52

There is a range of such products for other inborn errors of metabolism requiring dietary modification.

We would also support DAAs concerns regarding the labelling of low reduced lactose products – that the presence of galactose be clearly stated for the management of individuals for galactosaemia

Thank you for the opportunity to comment on this proposal

Mrs Sue Thompson
Dietitian Representative, Australasian Society for Inborn Errors of Metabolism