

# ADVISORY COMMITTEE ON BORDERLINE SUBSTANCES

## APPENDIX 1

### CATEGORISATION OF NUTRITIONAL PRODUCTS SUBMITTED FOR APPROVAL BY THE ADVISORY COMMITTEE ON BORDERLINE SUBSTANCES

**NOTES:** All the following categories can include formulations intended for both adult and paediatric use.

**Children (in the context of estimating nutritional requirements for enteral feeding) are usually defined as being 1 – 12 years of age and 8 – 45 kg in weight. While many specific paediatric enteral feeding products are available, it is sometime necessary to use an adult formulation to meet the needs of an individual child.**

#### CATEGORY 1

##### NON-DISEASE SPECIFIC ENTERAL TUBE FEEDS

**Note:** If these products, when used in accordance with the manufacturer's instructions, are claimed to provide the sole source of nutrition (with safe and appropriate levels of all macro / micronutrients) for each 24 hours for the persons for whom they are intended, they must comply with the guidance in the Information Notes (Para. 4.6.1)

- 1.1** Standard products (with or without fibre)
  - Adults: 1.0 kcal / ml and < 5.0g protein / 100ml
  - Children: 1.0 kcal / ml and < 4.0g protein / 100ml
- 1.2** Higher energy products (with or without fibre)
  - Adults: 1.1 - 1.4 kcal / ml and < 5.0 g protein / 100ml
  - Children: ≥1.5 kcal / ml and < 4.0g protein / 100ml
- 1.3** Energy and/or protein rich products (with or without fibre)
  - Adults: ≥ 1.5 kcal / ml and / or ≥ 5.0g protein / 100ml
  - Children: ≥1.5 kcal / ml and ≥ 4.0g protein / 100ml
- 1.4** Energy and / or protein reduced products (with or without fibre)
  - Adults: < 1.0 kcal / ml and / or ≤ 4.0g protein / 100ml
  - Children: < 1.0 kcal / ml and / or ≤ 2.4g protein / 100ml

## CATEGORY 2

### NON-DISEASE SPECIFIC ORAL NUTRITIONAL SUPPLEMENTS

**Note:** The nutrients provided in these products will not, on their own, meet all the identified daily nutritional needs of the persons for whom they are intended.

- 2.1 Standard products (with or without fibre)
  - Adults: 1.0 kcal / ml and < 5.0g protein / 100ml
  - Children: 1.0 kcal / ml and < 4.0g protein / 100ml
- 2.2 Higher energy products (with or without fibre)
  - Adults: 1.1 - 1.4 kcal / ml and < 5.0 g protein / 100ml
  - Children: ≥1.5 kcal / ml and < 4.0g protein / 100ml
- 2.3 Energy and/or protein rich products (with or without fibre)
  - Adults: ≥ 1.5 kcal / ml and / or ≥ 5.0g protein / 100ml
  - Children: ≥1.5 kcal / ml and ≥ 4.0g protein / 100ml
- 2.4 Energy and / or protein reduced products (with or without fibre)
  - Adults: < 1.0 kcal / ml and / or ≤ 4.0g protein / 100ml
  - Children: < 1.0 kcal / ml and / or ≤ 2.4g protein / 100ml

## CATEGORY 3

### NUTRITIONAL PRODUCTS FOR SPECIFIC CLINICAL CONDITIONS

**Note:** If these products, when used in accordance with the manufacturer's instructions, are claimed to provide the sole source of nutrition (with safe and appropriate levels of all macro / micronutrients) for each 24 hours for the persons for whom they are intended, they must comply with the guidance in the Information Notes (Para. 4.6.1).

- 3.1 Products in which there is removal or modification of energy and / or nutrients or where there is supplementation with energy and / or nutrients which are considered to confer significant clinical benefits in the management of disease and specific clinical conditions  
e.g. respiratory disease, liver disease, prematurity, glucose / galactose malabsorption
- 3.2 Products which have been specifically designed to enhance immune function, to reduce infection rates and, by virtue of specific metabolic effects on metabolism, to improve nutritional status in disease  
e.g. pancreatic cancer
- 3.3 Products for the clinical management of conditions of proven dietary allergy or intolerance in infants and children e.g. allergy to whole protein and / or disaccharide intolerance
  - Note:** This does not apply to foods in cases of dietary avoidance in adults when alternative dietary sources are available

## **CATEGORY 4**

### **NUTRITIONAL PRODUCTS DESIGNED FOR THE SPECIFIC MANAGEMENT OF INHERITED METABOLIC DISORDERS**

These products are specifically designed for use in the following indicative conditions and will not, on their own, meet all the identified daily nutritional needs of the persons for whom they are intended.

#### **4.1 Products suitable for specific inherited metabolic disorders**

- 4.1.1 Glutaric aciduria (Type 1)
- 4.1.2 Homocystinuria or hypermethioninaemia
- 4.1.3 Hyperlysinaemia
- 4.1.4 Isovaleric acidaemia
- 4.1.5 Maple syrup urine disease
- 4.1.6 Methylmalonic or propionic acidaemia
- 4.1.7 Phenylketonuria
- 4.1.8 Tyrosinaemia
- 4.1.9 Urea cycle disorders (other than arginase deficiency)
- 4.1.10 Fatty Acid Oxidation Disorders
- 4.1.11 Galactosaemia
- 4.1.12 Histidinaemia
- 4.1.13 Glycogen storage disease

#### **4.2 Special supplements for use in patients with inherited metabolic disorders**

## **CATEGORY 5**

### **STAPLE FOOD PRODUCTS DESIGNED TO OPTIMISE NUTRITIONAL STATUS AS PART OF THE CLINICAL MANAGEMENT OF FORMALLY DIAGNOSED CHRONIC DISEASE STATES**

**Note:** The nutrients provided in these products will not, on their own, meet all the identified daily nutritional needs of the persons for whom they are intended

## **5.1 Gluten Free Foods**

Foods which have been specially produced, prepared or processed to reduce their gluten content and which must not contain a level of gluten exceeding 20mg / kg (20 ppm)

For the management of established gluten sensitive enteropathy

Any other potential contaminants, e.g. oats contained in these products must have been specifically produced, prepared or processed to reduce their gluten content and this must not exceed 20mg / kg (20 ppm). This must be stated in the application.

An official signed certificate of declaration of the gluten content must be submitted with every type of application.

## **5.2 Low protein foods**

**5.2.1** for specific use in liver failure

**5.2.2** For use when a low protein diet is an essential part of the clinical management of an inherited metabolic disorder

**5.2.3** For use in other conditions requiring a low protein diet

## **CATEGORY 6**

### **NUTRITIONAL PRODUCTS DESIGNED TO ENHANCE THE SAFETY AND / OR ACCEPTABILITY OF FOODS OR FEEDS WHICH ARE PRESCRIBABLE IN ANY OF THE ABOVE CATEGORIES**

**Note:** The nutrients provided in these products will not, on their own, meet all the identified daily nutritional needs of the persons for whom they are intended.

## **6.1 Thickeners and pre-thickened foods**

For the management of dysphagia, infantile vomiting, nausea and vomiting in pregnancy

**6.1.1** Thickeners

**6.1.2** Pre-thickened foods and drinks

## **6.2 Flavourings**

To improve the acceptability of unpalatable formulations.

### **6.3 Mineral and vitamin preparations**

For supplementing restrictive diets where there is a diagnosed metabolic disorder.

### **6.4 Fibre preparations**

Specifically designed products for use as a supplement to be added to non-fibre-containing enteral feeds and formulae without affecting the nutritional content, other than providing additional energy from the fibre itself.

### **6.5 Artificial Salivas**

To enable the start of the digestive process in patients who have no saliva.