

# ADVISORY COMMITTEE ON BORDERLINE SUBSTANCES

## APPENDIX 6 – TO BE REVIEWED

### NUTRITIONAL PRODUCTS WHICH WILL NOT BE CONSIDERED BY THE ACBS

**Note: This should be read in the context of the entire guidance document**

#### **Introduction**

The Advisory Committee on Borderline Substances (ACBS) is specifically concerned with products which have proven clinical benefit in the management of formally diagnosed disease states and stringent criteria are applied to regulate the reimbursement of such products at NHS expense. Current awareness of nutrition and its importance in maintaining health has led to the introduction of a range of nutritional products about which many claims are made. However these may not be clinically substantiated / evidence based in a robust way and their introduction to the UK is market driven with much of the available supporting literature deriving from commercial sources.

#### **Background**

UK food legislation is based on regulations and directives agreed within the European Union (EU). The resulting European Commission (EC) documentation makes repeated reference to the need to ensure a high level of protection for consumers and this includes the requirement that any “health claims for foods should only be authorised for use in the Community after a scientific assessment of the highest possible standard” (Regulation (EC) No.1924 / 2006). This requirement is not met by many so-called nutraceutical products which some companies wish to bring to the market. Health claims made under Article 13 of the Health Claims Regulations have been submitted to the Commission and the substantiating science is to be assessed by the European Food Safety Authority (EFSA) before the final permitted list of health claims is agreed. The list is expected to be agreed during January 2010.

Some products that are not recognised as medicines (EC Directive 2001 / 83 / EC as amended by EC Directive 2004 / 27 / EC) nor as Traditional Herbal Medicines (Directive 2004 / 27 / EC) and which meet the definition of food as in Regulation (EC) No 178 / 2002 must comply with food law.

There is additional EC food legislation covering the following, more specific, aspects:

- \* PARNUTS Foods (Foods for Particular Nutritional Uses): Directive 89 / 398 / EEC
- \* Food Additives: Directive 89 / 107 / EC and amended by Directive 2001 / 125 / EC
- \* Addition of vitamins and minerals and certain other substances to foods:  
Regulation (EC) No 1925 / 2006

\* Food Supplements Directive 2002 / 46 / EC and amended by Directive 2006 / 37 / EC

It should be noted that this is not an exhaustive list.

### **Gluten Free Foods**

Regulations have been introduced that restrict the prescribing of gluten-free foods to breads and mixes only. Breads and mixes have been retained because the Government decided, following a public consultation, that patients should continue to receive some staple gluten-free foods on the NHS. Therefore, the ACBS will only consider applications for gluten-free foods where the food is both a staple and either a bread or a mix. All other gluten-free foods are not eligible for inclusion in Part XV of the Drug Tariff and will not be considered by the ACBS.

The National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) (Amendment) Regulations 2018 came into force on 4<sup>th</sup> December 2018 and prohibit the prescribing of all gluten-free and very low gluten foods in primary care except for gluten-free breads and mixes. Additionally, in recognising that many non-essential and luxury foods may be presented as breads and mixes, it was decided that the definitions of breads and mixes will extend only to staple foods. The definitions of the relevant terms to consider when making an application to the ACBS for a gluten-free food are as follows:

**Gluten Free:** A food which when sold to the final consumer contains no more than 20mg/kg of gluten and where it contains oats has been specially produced, prepared and/or processed in a way to avoid contamination by wheat, rye, barley, or their crossbred varieties.

**Very low gluten:** A food which when sold to the final consumer, contains no more than 100mg/kg of gluten and consists of, or contains one or more ingredients made from wheat, rye, barley oats, or their crossbred varieties which have been specially processed to reduce the gluten content, and where it contains oats; has been specially produced, prepared and/or processed in a way to avoid contamination by wheat, rye, barley or their crossbred varieties and the gluten content of the oats does not exceed 20mg/kg.

**Bread:** a food of any size, shape or form which is usually known as bread and consists of a dough, made from flour and water with or without other ingredients, which has been fermented by yeast or otherwise leavened and subsequently baked or partly baked.

**Mix:** A mixture of two or more ingredients which is to be combined with any one or more additional ingredients and baked or otherwise cooked.

**Staple food:** is one that is eaten regularly and in such quantities as to constitute the dominant part of the diet and supply a major proportion of energy and nutrient needs.

Examples of foods that are eligible include: breads in loaf, rolls and baguette presentations; and multipurpose and bread mixes.

Examples of foods that are not eligible include: biscuits, cooking aids, grains and flours, pasta, ready meals, cereals, cakes and pastries.

**Nutraceuticals** have been described as “substances which are not traditionally recognised nutrients but which have positive physiological effects on the human body”. They are generally marketed in the context of health promotion / disease prevention rather than disease management and, as such, have greater appeal for the “worried well”. There is no legal definition of the term 'nutraceutical' nor are they currently regulated on a European-wide basis leaving each member state free to apply its own regulatory framework. This has led to confusion with such products being available in some countries and not in others as well as being categorised differently between countries. This presents a significant challenge to companies trying to market these products throughout Europe.

Because there is no legal definition of the term “nutraceutical products” nor any separate regulations, products are either regulated as foods or medicines. The Medicines and Healthcare products Regulatory Agency is not aware of any plans to amend the definition of a medicinal product or alter food legislation to make specific provision for nutraceuticals. This means that for any such products to be regulated by the legislation applicable to foods there can be no suggestion that the product can treat or prevent disease. A food (or foodstuff) is defined as “any substance or product whether processed, partially processed or unprocessed intended to be, or reasonably expected to be, ingested by humans” (Regulation (EC) No 178 / 2002)

Regulation (EC) No 1924 / 2006 governing nutritional and health claims for food has been introduced by the EC and this will, undoubtedly, impact on the marketing of nutraceuticals and other similar products. As required by this legislation, the Commission is, currently, establishing specific nutritional profiles which may restrict the use of health claims based on the nutritional composition of the food. The profiles will be in place by January 2009 and foods bearing nutrition or health claims must comply by January 2011.

Safe levels of vitamins and minerals have already been established in the case of Foods Used for Special Medical Purposes (Directive 1999 / 21 / EC). Regulation (EC) No 1925 / 2006 on the addition of vitamins, minerals and of certain other substances puts in place provision to set safe maximum levels for fortified foods. The Commission must submit proposals for maximum safe levels by January 2009.

In the meantime, the ACBS will **only** consider applications for such products in the context of specific clinical conditions and diagnosed disease management where there is robust evidence of clinical efficacy and effectiveness. The Committee will expect any such applications to be clearly defined as disease specific formulations supported by evidence as described in Appendices 4 and 5

**Food supplements** are defined as “foodstuffs, the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles and other similar forms of liquids and powders designed to be taken in measured small unit quantities (Directive 2002 / 46 / EC and amended by Directive 2006 / 37 /

EC). Some such products are considered by the ACBS. However, this is only within the context of a formally diagnosed clinical condition and any such product would be formally prescribed as an integral part of the clinical management of that disease.

## Conclusions

In summary, there does not appear to be a case for the ACBS to include consideration of nutraceutical and other similar products within its remit pending further EC legislation. When this is available, the situation will be reviewed.

The following products will not, therefore, be considered by the ACBS

- Foods for particular nutritional uses which have been designed to help in the management of a range of situations and which are widely available on a commercial basis e.g. standard infant / follow-on formulae, infant foods, weight reducing and diabetic products, “sports” foods.
- Everyday foods which have been manipulated to enhance their disease prevention / disease management properties e.g. spreads made with plant sterols, yoghurts containing probiotics.
- Functional foods or so-called “superfoods” which are naturally occurring but which contain higher levels of specific substances associated with improved health e.g. antioxidants, flavonoids.
- Everyday foods which, by virtue of the location from which they are sourced, contain higher than normal levels of identified substances which might be considered to have beneficial nutritional properties.
- Foods to which additional nutrients / other substances have been added (sometimes in excess of the maximum permitted safe levels) specifically to enhance their health giving properties.
- Food / dietary supplements which are normally available over the counter including minerals, vitamins and other similar products.
- “Luxury” foods designed to enhance compliance with the long term management of chronic disease. These include special recipe dishes / products for use in common conditions such as diabetes and coeliac disease which, although useful, are not fundamental to disease management.

**Note:** Further information about this will be available in due course

- Any product where, in the opinion of the Committee, there is an equivalent pharmaceutical licensed medicinal product.