

Scientific Advisory Committee on Nutrition

Omneo Comfort 1: Application for inclusion in the Welfare Food Scheme

1. Issue

The Committee is asked to consider the application by Cow & Gate/Nutricia to the Department of Health for inclusion of the infant formula “Omneo Comfort 1” in the Welfare Food Scheme.

2. Background

2.1 The Welfare Food Scheme (WFS) has been in operation in the UK since 1940. It provides a nutritional benefit in kind, rather than in cash, which is mainly aimed at pregnant women and breastfeeding mothers with children under 5 years in low-income families. The main part of the scheme involves the issue of milk tokens, which can be exchanged for 7 pints of milk per week or, for infants aged 1 year and under, 900 grams of infant formula. Vitamin supplements are also available free of charge (see Annex 1).

2.2 Infant formula included in the WFS must comply with current regulations on safety and compositional requirements and have proven health benefits to healthy infants. COMA’s Panel on Child and Maternal Nutrition (PCMN) has published guidelines on the assessment of infant formulas. The key recommendations are at Annex 2. COMA guidelines have also been recently endorsed by the European Society of Paediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN).

2.3 Omneo Comfort 1 is targeted at mothers who report that their infants have minor digestive and feeding problems such as colic, passing hard stools and regurgitating small amounts of feed. Unique features of Omneo Comfort 1 are the inclusion of a mixture of prebiotic oligosaccharides and a structured triglyceride called Betapol.

2.4 The manufacturer states that the mixture of oligosaccharides (fructo-oligosaccharides and galacto-oligosaccharides) in Omneo Comfort 1 may play an important role in promoting the growth of different species of bifidobacteria. The development of bifidobacteria rich microflora in the gut may be important for the health of infants as studies have shown that it inhibits both gram positive and negative pathogenic bacteria, can have a stimulatory effect on the immune system and promotes the production of B vitamins. The scientific data to support health benefits of this oligosaccharide mixture in infants is included in the Cow & Gate submission (see Annex 3).

2.5 The palmitic acid in Betapol is predominantly esterified in the sn-2 position, as is the palmitic acid in human milk fatty acids. In contrast, the palmitic acid in other infant formulas is predominantly esterified in the sn-1 and sn-3 positions. Palmitic acid in the sn-2 position is more efficiently absorbed than in the sn-1 and sn-3 positions and form less calcium soaps within the intestinal lumen resulting in softer stools (Annex 3).

3. Current position

3.1 The key changes in the new formula are the addition of Betapol and Oligosaccharides - both these ingredients are allowed under the current EC Regulations on Infant Formulas (Annex 4). However, there are on going discussions at the European Commission regarding their use. In particular questions have been asked about the safety and health benefits of oligosaccharides in infant formula.

3.2 The UK Advisory Committee cleared Betapol, as a novel ingredient for use in foods on Novel Foods and Processes (AFCNP). The specific issue of its suitability for use in infant formulas was referred to COMA's Panel on Child and Maternal Nutrition (PCMN). PCMN assessed the issue and stated that more long term follow up data was required before Betapol's suitability for inclusion in infant formula could be established and the issue remained unresolved. Meanwhile, new EC regulations came into force under which Betapol no longer needed final clearance as a novel food because it was already being marketed and had a history of use in some EC countries. Therefore, the manufacturer did not pursue COMA's request for long-term follow up data.

3.3 Omneo Comfort 1 is now available in the UK and is currently promoted in the professional press. A copy of an information sheet produced by the manufacturers for health professionals and example of the formula packaging are attached at Annex 5 and 6 respectively.

Members are requested to:

- **Consider** whether there are any specific safety concerns that arise in respect to the addition of Betapol and the mixture of oligosaccharides to infant formula.
- **Consider** whether the evidence presented is sufficient and in accordance with COMA's 'Guidelines on the Nutritional Assessment of Infant Formulas'.
- **Advise** whether the evidence presented by Cow & Gate-Nutricia relating to the addition of oligosaccharides to infant formula, would provide a functional or clinical benefit to healthy infants.
- **Advise** whether there are any scientific objections to Omneo being included in the Welfare Food Scheme.

