

# **Opinion on Certain Additives for Use in Foods for Infants and Young Children in Good Health and in Foods for Special Medical Purposes for Infants and Young Children (expressed on 21 March 1997 and amended on 13 June 1997)**

*N.B. This is the full text of the opinion which was adopted at the 106th Meeting of the SCF on the 21 March 97.*

*It should be noted that, when adopting this final text at its 107th Meeting, the Committee amended its conclusions with regard to L-ascorbyl palmitate (E 304) and Diacetyl tartaric acid esters of mono- and diglycerides of fatty acids (E 472e) - DATEM.*

## **Terms of reference**

To consider the safety-in-use of certain additives in infant formulae, follow-on formulae and weaning foods for infants and young children in good health and in foods for special medical purposes (FSMP) for infants and young children.

## **Background**

The use of additives in foods for infants and young children in good health and in FSMP for the same age group is controlled under European Parliament and Council Directive 95/2/EC on food additives other than colours and sweeteners.<sup>1</sup> This restricts the additives permitted in infant formulae, follow-on formulae and weaning foods for infants and young children in good health to those listed in Parts 1-3 of Annex VI to the Directive. The use of additives in FSMP for infants and young children is controlled under Part 4 of Annex VI of the same Directive; this permits all the additives listed in Parts 1-3 to be used in FSMP, with no additional additives currently permitted exclusively for FSMP.

The Association of the Food Industries for Particular Nutritional Uses of the European Union (IDACE) has requested amendment of Directive 95/2/EC to include additional additives in for use in foods for infants and young children in good health and for use in FSMP for the same age group.<sup>2-5</sup> In some cases particular additives have been requested for both categories (good health and FSMP) and in other cases for just one category or the other. Some of the requests to use the same additive in both categories relate to use in products containing hydrolysed proteins which have special technical requirements (e.g. products for cow's milk allergy); such products are marketed as FSMP and/or as foods for infants and young children in good health.

The Scientific Committee for Food (SCF) has recently given an opinion on the use of certain colours for FSMP for young children aged 12-36 months of age.<sup>6</sup> The present opinion covers certain additives other than colours, most of which are emulsifiers, stabilisers or thickening agents. The additives requested and the recommendations of the Committee are listed in the table "Summary of Recommendations " at the end of this opinion and are considered individually below.

## **General considerations of need**

In considering the request to use additional additives, the Committee was mindful of the principle set out in its earlier reports that it is prudent to keep the number of additives used in foods for infants and young children to the minimum necessary.<sup>7,8</sup> The Committee has stressed in the past that there should be strong evidence of need as well as safety before additives can be regarded as acceptable for use in infant formulae and foods for infants and young children. The

Committee continues to endorse these principles, but is aware, for reasons explained below, that the nature of FSMP is such that they may require a wider range of additives than those already permitted for foods for infants and young children in good health and/or they may require a higher level of addition of an additive already permitted for foods for infants and young children in good health. The Committee is also aware that, for historical reasons, different manufacturers of FSMP have developed products over long periods of time utilising different additives which may nevertheless have the same technological function. However, the Committee wishes to record that it is not always easy to reach a view on case of need.

FSMP for infants and young children encompass a wide variety of different products in powdered, liquid or semi-solid forms, each with a specific formulation and hence each with its own technological requirements. They are generally either of the "elemental" type (formulae containing free amino acids, glucose syrup or maltodextrin and a low fat content) or "semi-elemental" type (containing hydrolysed proteins, maltodextrin and fat), together with vitamins, minerals and trace elements. The fats and starches used may also be unusual compared to those used in foods for infants and young children in good health. Thus the technological requirements for additives for FSMP may differ considerably from those for foods for infants and young children in good health.

Normal infant formulae based on cow's milk benefit from the inherent properties of the ingredients they contain, in particular whole proteins which act as efficient emulsifiers. Products containing hydrolysed proteins, peptides or free amino acids lack the normal emulsifying properties of whole protein and so the use of additives such as emulsifiers with a high hydrophylic-lipophylic balance (HLB) value is necessary to enable lipids and carbohydrates of very high molecular weight to interact. This limits the separation of the fatty phase in ready-for-consumption liquid products, notably when products are formulated with modified fats.

The only thickening agent or stabiliser which is permitted in infant formulae for infants in good health is starch. Native starches tend to lose their thickening properties when processed, cooled and stored. Products formulated with protein hydrolysates, peptides or free amino acids require added thickening agents and stabilisers to influence viscosity both during sterilisation and at room temperature, to avoid separation of the various elements such as fibres in liquid feeds, and to reduce the coalescence of fat globules, especially in products in liquid, ready-to-consume form which may be stored for several months. The particular oils and fats used in certain products may also require the addition of thickening agents which are adapted to their special properties.

Against this background, the specific considerations of need for each of the additives requested for foods for infants and young children in good health and for FSMP for the same age group have been carefully considered by the Committee. For each additive requested for FSMP, the Committee was also informed about the range of medical conditions requiring such foods which might contain that additive and the estimated levels of intake of each additive in the various age groups.<sup>2-5</sup>

It is to be noted that unless otherwise stated, reference to FSMPs in the following evaluations is to be understood as covering FSMPs intended for infants and young children from birth onwards.

## **Consideration of individual additives**

### **Distarch phosphate (E1412)**

Distarch phosphate has been requested for use up to 10g/l (reconstituted dry powders) and 22g/l (liquids) in infant formulae and follow-on formulae for infants and young children in good health and in FSMPs. It is a chemically modified starch containing <0.02% phosphorus and is used as a stabiliser, thickening agent and binder. Infant formulae containing modified milk proteins or soy proteins and insoluble salts (as calcium) require a stabilising agent to prevent protein precipitation during sterilisation or storage. The Committee has been informed<sup>2</sup> that starches cross-linked with phosphorus, such as distarch phosphate, have higher stability during shear stress and heat sterilisation. The Committee notes that distarch phosphate is included in the list of additives permitted by the Codex Alimentarius in soya-based infant formulae (5g/l) and in hydrolysed protein and/or amino acid based infant formulae (25g/l).

Distarch phosphate was assigned an Acceptable Daily Intake (ADI) "not limited" by the FAO/WHO Joint Expert Committee on Food Additives (JECFA) in 1973.<sup>10</sup> Modified starches for general food use and for use in baby food were also considered by the SCF in 1976 and in 1981.<sup>11</sup> Both JECFA and the SCF have considered the kidney lesions which occur in rats fed high levels of modified starches. They concluded that the rat is a particularly sensitive species for pelvic nephrocalcinosis and the finding has little relevance for safety evaluation of modified starches in man and JECFA confirmed an ADI "not specified".<sup>11,12</sup> In its report on weaning foods,<sup>13</sup> the SCF concluded that use of distarch phosphate singly or in combination with other starches was acceptable to a limit of 5g/100g. In 1992, the SCF reviewed the suitability of distarch phosphate for use in infant formulae and concluded that distarch phosphate should not be permitted in infant formulae. 8

Consideration of the digestibility of starches is also relevant. Adults digest starch mainly by the action of pancreatic amylase but infants have a very low activity of this enzyme.<sup>14</sup> Instead, mucosal glucoamylase and salivary amylase are sufficient in some infants to digest long-chain glucose-polymers.<sup>15</sup> It has also been shown that infants are capable of digesting cooked native starches from 1 month of life.<sup>16</sup> However, large amounts (40g/day) of starches in the diet given to 1 month old infants resulted in malabsorption and fermentative diarrhoea.<sup>16</sup> It has also been suggested that undigested starch in the gastro-intestinal tract may interfere with other food ingredients resulting in failure to thrive in some infants.<sup>17</sup> The SCF has concluded that pre-cooked or gelatinized starch (but not native or chemically modified starches) can be added to infant formula up to 2g/100ml, but not exceeding 30% of the total carbohydrate content.<sup>7</sup> An addition of 2g starch/100 ml corresponds to an estimated intake of 10g/day. Consequently, there is no wide margin between the permitted level of native starches and the level of 40g starch per day, where effects have been observed.

*In vitro studies using human and rabbit pancreatic amylases and in vivo studies in adult rabbits show that the digestibility of waxy corn distarch phosphate and native starches is comparable.<sup>18</sup> However, this study may be of little relevance for the digestibility of modified starches in infants due to low levels of pancreatic amylase, but as pointed out in the opinion by the Committee in 1992,<sup>8</sup> the spectrum of activity of alpha-amylase in saliva and pancreatic secretion is the same since the amino-acid sequence is identical.<sup>19</sup> Nevertheless, it is not known how the efficacy of the alpha-amylase in saliva compares with the pancreatic form due to possible effects on the enzyme of, for example, gastric juice.*

**Conclusion:** In its 1992 opinion<sup>8</sup> the SCF recommended distarch phosphate should not be permitted in infant formulae because the Committee would prefer to see direct evidence indicating that infants can tolerate the 2.5% level of modified starches then requested. The current request is for use up to 2.2%. A concern was also raised that infants could develop fermentative diarrhoea or modification of the gut flora. No new information on these aspects have been found. Furthermore, the Committee is not persuaded there is a need for use of distarch phosphate in infant formulae generally. A case of need could be valid for formulae containing hydrolysed proteins (whether for children in good health or FSMP), but at present the Committee has insufficient information to reach a conclusion on this point. In the meantime the Committee does not consider that the use of distarch phosphate is acceptable in infant formulae, follow-on formulae for infants and young children in good health or in FSMP.

## **Sodium citrate (E331) and potassium citrate (E332)**

Sodium citrate and potassium citrate have been requested for use from birth, either singly or in combination at levels up to 2g/l, in infant formulae and follow-on formulae for infants and young children in good health and in FSMP.<sup>2</sup> The heating procedure for infant formulae or follow-on formulae made from cow's milk results in denaturation and aggregation of proteins. In extreme cases the result is a phase separation of fat and proteins. The Committee has been informed<sup>2</sup> that the addition of sodium citrate and potassium citrate improve heat stability. During heat treatment casein in milk coagulates due to surplus ionized calcium. The addition of sodium or potassium citrate complexes free calcium ions, resulting in decreased coagulation. The same technological function can also be performed by sodium and potassium phosphates (see below) and all four additives have been requested so that alternatives are available (e.g. in cases where no additional phosphate load can be tolerated). Sodium and potassium citrates are already permitted under Directive 95/2/EC in weaning foods at quantum satis levels for pH adjustment only,<sup>1</sup> and under Directive 91/321/EEC as sources of nutrients in infant formula and follow-on formula for infants and young children in good health.<sup>9</sup>

**Conclusion :** The Committee considers the use of sodium and potassium citrates are acceptable up to 2g/l, either singly or in combination, in infant formulae and follow-on formulae for infants and young children in good health and in

FSMP.

## **Sodium phosphate (E339) and Potassium phosphate (E340)**

Sodium phosphate and potassium phosphate have been requested for use from birth, either singly or in combination, at levels up to 1g/l (expressed as P<sub>2</sub>O<sub>5</sub>), in infant formulae and follow-on formulae for infants and young children in good health and in FSMP.<sup>2</sup> Their technological function is the same as that for sodium and potassium citrates (see above). The use of sodium and potassium phosphates in weaning foods and cereals for infants and young children is permitted under Directive 95/2/EC, either singly or in combination up to a maximum of 1g/kg (expressed as P<sub>2</sub>O<sub>5</sub>).<sup>1</sup> These additives are also permitted as nutrients in infant formulae and follow-on formulae under Directive 91/321/EEC.<sup>7,9</sup> In 1992, the Scientific Committee for Food also concluded that the use of phosphoric acid (E338) in infant formulae was acceptable.<sup>8</sup>

Sodium phosphate and potassium phosphate were evaluated by JECFA in 1982.<sup>12</sup> Of greatest concern was the toxicity arising from excess of phosphorus (P) in the diet and deficiencies in calcium (Ca). A high dietary phosphate intake in animals results in hypocalcaemia which stimulates secretion of parathyroid hormone. This hormone inhibits tubular reabsorption of phosphates by the kidney and increases demineralization of bone tissue. P is mainly excreted in faeces as calcium phosphate, so that intake of excessive amounts of sodium phosphate and phosphoric acid may cause a loss of Ca. The main toxicological finding in animal feeding studies with phosphates is nephrocalcinosis, the rat being highly susceptible. An estimate of the lowest level of dietary intake of phosphates (expressed as P) that might cause nephrocalcinosis in man is about 7000mg P/day. Since P is an essential nutrient, JECFA allocated a Maximum Tolerable Daily Intake (MTDI) rather than an ADI. The MTDI of 70mg/kg b.w. applies to the sum of phosphates naturally present in food and derived from additives in the diet, for diets that are nutritionally adequate with respect to Ca.<sup>12</sup>

Old data indicate that high-phosphorus human milk substitutes may contribute to hypocalcaemic tetany in infants. However, when artificial formula simulated breast milk, the occurrence of tetany decreased.<sup>20</sup> Cow's milk contains more Ca and more P than human milk. The Ca:P ratio in cow's milk is 1.35:1 and in human milk 2.25:1. On the other hand, infants absorb 85-90% of the P in human milk and 65-70% of that in cow's milk.<sup>21</sup>

The RDA (Recommended Dietary Allowance) for P for formula-fed infants from birth to 6 months of age is 300mg/day, and 500mg/day for infants aged 6-12 months.<sup>21</sup> Allowances for P are based on a Ca:P ratio of 1.3:1 (the same as in cows' milk) during the first 6 months of life and 1.2:1 for the following 6 months. Thus, for newborn infants, the RDA is around the same level as the MTDI for adults. The Committee therefore considers that the MTDI as an upper limit is not applicable to infants.

At the requested level of 1g/l for E339 and E340 (expressed as P<sub>2</sub>O<sub>5</sub>), the P content of formula would be 440mg P/l (P is 40% of phosphate). The mean consumption of infant formula is 700-850ml/day in infants aged 1-3 months, with a range of 500-1100ml/day,<sup>22</sup> and the 90th percentile consumption is about 1 l/day. Thus, the estimated 90th percentile intake of P from use of E339 and E340 would be 440mg P/day. This represents 150% of the RDA.

*Conclusion:* The estimated 90th percentile intake of P, although above the RDA for infants, is unlikely to be harmful. While knowledge about toxicity from P intake in infants is limited, there are no indications that there would be adverse health effects at the intakes resulting from the use of E339 and E340 at the requested level, provided the Ca:P ratio is kept within the recommended limits set out in Annex 1 to Directive 91/321/EEC.<sup>9</sup> The Committee considers the use of sodium phosphate and potassium phosphate, either singly or in combination, up to 1g/l (expressed as P<sub>2</sub>O<sub>5</sub>) is acceptable in infant formula, follow-on formula and FSMP.

## **Locust bean gum (E410)**

Locust bean gum has been requested for use in infant formula and follow-on formula, both for infants and young children in good health and in FSMP, at levels of 4-10g/l, to reduce gastro-oesophageal reflux (GOR). Locust bean gum, also called carob bean gum, is refined from the endosperm of the carob tree, *Ceratonia siliqua*. It contains tannins and the carbohydrate component is a galactomannan polymer consisting of linked D-mannose units with side chains of

D-galactose. It is used as a stabiliser and thickening agent. It is currently allowed in follow-on formulae at a maximum level of 1g/l, and in weaning foods at a maximum level of 10g/kg under Directive 95/2/EC.<sup>1</sup> The SCF has previously considered a request to use locust bean gum at a level of 1g/l in infant formula but at that time there was no confirmation of need.<sup>8</sup>

The Committee is aware that some medical specialists (ESPGAN) recommend that thickening of foods is useful in the treatment of GOR, and that in cases of uncomplicated GOR, treatment with thickening agents may be started without complementary investigations.<sup>23</sup> Clinical observations have shown that the clinical efficacy is best when locust bean gum is added to infant formula in the concentration range 4-10 g/l.<sup>2</sup> However, there are few controlled studies of the efficacy of use of thickened infant formula in reducing GOR. It is believed that the increased viscosity of thickened feed will reduce the episodes of reflux, but it has been shown that the effects are unpredictable.<sup>24-26</sup> Thickeners added to infant formula may reduce the number of reflux episodes, but may also prolong the duration of remaining episodes.<sup>27</sup> Increased coughing in infants after thickened feedings compared with after unthickened feedings has also been reported.<sup>28</sup>

Locust bean gum was evaluated by JECFA in 1981.<sup>29</sup> An ADI not specified was allocated due to lack of toxicity. In an unpublished three-generation reproduction study referred to by JECFA, significant decreases in pre-mating body weight gain in the F0 females fed 2% locust bean gum, and final body weight in the females fed 5% locust bean gum were observed. No significant effect on body weight gain was observed in newly weaned rats fed a diet containing 2% locust bean gum for 36 days.<sup>30</sup> On the other hand growth was depressed in chickens fed a diet containing 2% locust bean gum for 24 days.<sup>30</sup> Thus there are indications of growth depression in animals fed locust bean gum, although these are equivocal.

Bean gum preparations are fermented in the colon, providing a small energetic gain. They can cause abdominal pain and diarrhoea.<sup>23</sup> Absorption of minerals and trace elements may be reduced by dietary fibre and tannins. Although a study on adults ingesting locust bean gum has shown no evidence of impaired absorption of minerals and trace elements,<sup>31</sup> it is not always appropriate to use results from adults when evaluating health effects in infants in cases where growth may be affected. In rapidly growing healthy infants, even minor effects on gastro-intestinal absorption of trace elements and minerals may have growth retarding effects. Studies on growth in healthy infants chronically exposed to locust bean gum are lacking.

*Conclusion:* The Committee is not persuaded that it is necessary to give thickened infant formula to infants in good health. It therefore recommends that the use of locust bean gum is not acceptable, at the doses requested, for use in infant formula and follow-on formula intended for infants in good health. The Committee does however accept that there is a case of need for its use in FSMP to treat GOR and recommends that its use in these products up to 10g/l is acceptable.

## **Mono- and di-glycerides of fatty acids (E471)**

Use of this emulsifier has been requested for FSMP at levels up to 5g/l in powdered and liquid formulations intended for infants and young children from birth onwards.<sup>2</sup> It is currently permitted under Directive 95/2/EC in infant formulae and follow-on formulae for infants in good health up to 4g/l and in weaning foods for infants and young children in good health up to 5g/kg.<sup>1</sup> The Committee has been informed<sup>2</sup> that a slightly higher level of E471 is required, for use in combination with other emulsifiers, for amino acid and peptide-based nutritionally complete FSMP which contain fat requiring an emulsifier of intermediate HLB value.

This emulsifier has not previously been individually considered by the SCF. The basic EC Directive on Emulsifiers, Stabilisers, Thickeners and Gelling Agents for use in Foodstuffs<sup>32</sup> was agreed in 1974, before the SCF was constituted. That Directive permitted over 65 additives, some temporarily. The first SCF Report on Emulsifiers, Stabilisers, Thickeners and Gelling Agents<sup>33</sup> published in 1978, explains that the Committee was asked to review only certain of the additives in the Directive. The review included the E472 group of emulsifiers but did not include E471. However, since the E472 group are derived from E471 (they are the acetic, lactic, citric, tartaric and diacetyl tartaric acid esters of mono- and di-glycerides of food fatty acids), it can be assumed that the SCF was content to go along with the Acceptable Daily Intake (ADI) "not limited" for E471, confirmed by the FAO/WHO Joint Expert Committee on Food

Additives (JECFA) in 1974.<sup>34</sup>

*Conclusion* : The Committee considers that the use of E471 is acceptable at levels up to 5g/l in all FSMP.

### **Citric acid esters of mono- and di-glycerides of fatty acids (E472c)**

This emulsifier has been requested for use from birth onwards in dry formulae up to 7.5g/l and in UHT-liquid formulae up to 9g/l which contain partially or extensively hydrolysed proteins both for infants and young children in good health and for FSMP.<sup>2</sup> Under Directive 95/2/EC, it is not currently permitted for use in infant formulae or follow-on formulae for children in good health but is permitted up to 5g/kg in weaning foods for children in good health.<sup>1</sup> The Committee has been informed<sup>2</sup> that E472c is needed, in addition to the emulsifiers already permitted, for products based on hydrolysed proteins or amino acids with high levels of fat, requiring emulsifiers with high HLB value. The E472 series of emulsifiers have high HLB values.

In its 1978 review,<sup>33</sup> the SCF concluded that the use of E472c was acceptable for foods generally and, in effect, endorsed the ADI set by JECFA in 1974, allocating an ADI "not specified" for E472c.<sup>34</sup>

*Conclusion* : The Committee considers that the use of E472c is acceptable in products which contain partially hydrolysed proteins for infants and children in good health and for FSMP containing extensively hydrolysed proteins or amino acids at levels up to 7.5g/l in ready-to-feed products made from dry powder and up to 9g/l in ready-to-use UHT-liquid formulae.

### **Diacetyl tartaric acid esters of mono- and diglycerides of fatty acids (E472e)**

This emulsifier, also known as DATEM, has been requested for use from birth onwards up to 3g/l in reconstituted powders and up to 4g/l in liquid formulations which are devoid of whole protein, both for children in good health and for FSMP, and up to 5g/kg in gluten-free bakery products for coeliac patients.<sup>2</sup> It is not currently permitted in infant formula, follow-on formula or weaning foods for infants and children in good health.<sup>1</sup> The Committee has been informed<sup>2</sup> that it is a suitable emulsifier, in combination with other already permitted emulsifiers, for hydrolysed protein, peptide and amino acid-based products, having very large hydrophilic polar groups which are particularly suitable for multi-component systems.

In its 1978 review, the SCF concluded that the use of DATEM was acceptable for foods generally and, in effect, endorsed the ADI set by JECFA in 1974, allocating an ADI of 0-50 mg/kg b.w.<sup>33</sup> The SCF has now updated its view on DATEM and, for reasons explained in a separate opinion<sup>57</sup>, has withdrawn the ADI of 0-50 mg/kg b.w. and set a temporary ADI of 0-25 mg/kg b.w.

*Conclusion* : The Committee temporarily accepts the use of DATEM in FSMP, but at a lower level than that requested for foods which are given as liquid formulations (whether reconstituted from dry powder or from liquids). The use of DATEM is temporarily acceptable for a period of 2 years at levels up to 0.4 g/l, as consumed, in FSMP which are devoid of protein, and up to 5g/kg in gluten-free bakery products for coeliac patients. The Committee is aware that a limit of 0.4 g/l may still mean that some infants and young children could exceed the temporary ADI of 0-25 mg/kg b.w.. However, the Committee has also taken into account the essential nature of these FSMPs for infants and young children with certain diseases and the considerable technical problems in manufacturing these FSMPs. Furthermore, the Committee will review the situation in 2 years' time. In the meantime the use of DATEM in foods for infants and young children in good health is not acceptable.

### **Sucrose esters of fatty acids (E473)**

Sucrose esters of fatty acids has been requested for use as an emulsifier up to 120mg/l in powdered and liquid FSMP containing partially or fully hydrolysed proteins or amino acids for infants and young children from birth onwards, and in liquid infant formula and follow-on formula containing partially hydrolysed or fully hydrolysed proteins for infants and young children in good health.<sup>2</sup> It has been permitted as an emulsifier in the EU in foods generally (except for

bread unless authorised for that use nationally) since 1974<sup>32</sup> and in dietetic foods.<sup>35</sup> It is not currently on the list of permitted additives for foods for infants and young children in good health.

Sucrose esters of fatty acids were evaluated by the SCF in 1992, when a Group ADI of 0-20 mg/kg b.w. (expressed as sucrose monostearate) was allocated for sucroglycerides and sucrose esters derived from palm oil, lard and tallow fatty acids, subject to a specification which would limit the presence of tetra- and higher esters to no more than 7%.<sup>36</sup> This opinion was based on information that the lower fatty acid esters of sucrose are hydrolysed in the gut to the constituent fatty acids and sucrose, which are well-known components of food. It has been considered several times by JECFA and, in its most recent evaluation in 1995, also given an ADI of 0-20 mg/kg b.w. expressed as sucrose ester content.<sup>37</sup> The only adverse effects noted in humans from sucrose esters of fatty acids are gastro-intestinal disturbances (soft stools, diarrhoea, flatulence and bloating) seen at intakes of 70 mg/kg b.w./day, with a no-effect level of 35 mg/kg b.w./day.

Intake estimates from the use of E473 in ready-to-use liquid formulae used as FSMP for infants and young children from birth up to 3 years of age range from 15-20 mg/kg b.w./day, which is just within the ADI. It is unlikely that the ADI for E473 would be exceeded on a regular basis since E473 is not permitted in other foods specially prepared for infants and young children.

*Conclusion* : The Committee considers that the use of sucrose esters of fatty acids is acceptable up to 120mg/l in powdered and liquid FSMP containing *extensively or* fully hydrolysed proteins or amino acids for infants and young children, and in liquid infant formula and follow-on formula containing partially hydrolysed proteins intended for infants and young children in good health.

## **Sodium alginate (E401)**

Sodium alginate has been requested as a stabiliser to be used in FSMP up to a level of 1g/l, in products intended for infants and young children with metabolic disorders and for general tube-feeding from 6 months of age onwards.<sup>2</sup> The Committee has been informed<sup>2</sup> that its use in combination with other stabilisers and emulsifiers reduces the overall intake of any one additive in products for metabolic disorders, and in tube feeds its use in combination with other thickeners and gelling agents prevents separation of fibre in the liquid feed.

The SCF has already recommended sodium alginate is acceptable as an additive in weaning foods for infants and young children in good health, for use in desserts and puddings at levels up to 0.5g/kg.<sup>8</sup> It is permitted for these uses under Annex VI of Directive 95/2/EC.<sup>1</sup> It has a JECFA Group ADI "not specified" for alginic acid and its ammonium, calcium, potassium and sodium salts.<sup>38</sup> No estimates of intake for E401 are given in the various submissions but intakes from FSMP would almost certainly be higher than that from its use in desserts and puddings for infants and young children in good health. A worst case estimate, assuming that the products concerned are the sole source of nutrition and consumption of 1l of product at 6 months rising to 2 l of product by 3 years of age, gives intakes of 130-140 mg/kg b.w./day for E401.

*Conclusion* : The Committee considers that the use of sodium alginate is acceptable up to a level of 1g/l in FSMP used from 4 months of age onwards.

## **Propane-1,2-diol alginate (E405)**

Propane-1,2-diol alginate has been requested as a stabiliser for use up to levels of 0.2 g/l in FSMP intended for young children from one year of age onwards who have cow's milk intolerance or inborn errors of metabolism.<sup>2</sup> The Committee has been informed<sup>2</sup> that it has stabilising properties and is synergistic with other emulsifiers; it enables the development of acidic products containing fat, which means that citrus flavouring may be added to mask the bitter taste of amino acids. It is permitted under Annex IV of Directive 95/2/EC in a variety of foods including FSMP (for children over 3 years of age and adults) up to 1.2 g/l, but is not listed in Annex VI which covers food additives permitted for infants and young children.<sup>1</sup>

E405 was listed in the basic 1974 EEC Directive on Emulsifiers, Stabilisers, Thickeners and Gelling Agents for use in

Foodstuffs<sup>32</sup> but the SCF did not review E405 until 1990 when an ADI of 0-25 mg/kg b.w. was allocated.<sup>39</sup> JECFA allocated it an ADI of 0-70 mg/kg b.w. in 1993.<sup>40</sup> Estimated intakes of E405 from nutritionally complete FSMP are 26-27 mg/kg b.w./day for children aged 12-36 months,<sup>2</sup> which is marginally above the SCF ADI and below the JECFA ADI. Alginates in general and propane-1,2-diol are of low toxicity and regular consumption just above the ADI would not be expected to pose any health problems.

*Conclusion* : The Committee considers that use of propane-1,2-diol alginate is acceptable up to levels of 0.2 g/l in FSMP intended for young children from one year upwards.

## **Carrageenan (E407)**

Carrageenan has been requested for use in FSMP at levels up to 0.3 g/l in ready-to-use liquid formulae given from birth onwards which contain extensively hydrolysed protein and/or amino acids.<sup>2</sup> In these products it acts to increase viscosity, delaying fat separation and so giving a longer shelf life. The products concerned are for children with intractable diarrhoea and other malabsorption conditions and with inborn errors of metabolism.<sup>2</sup>

In 1994 carrageenan was regarded by the Committee as not acceptable for use in infant formulae for infants in good health<sup>8</sup> and is currently being reviewed again by the SCF in relation to food use generally. The Committee currently has serious reservations about its use in very young infants because of possible uptake by the immature gut and the possibility of effects on the immature immune system. In the context of FSMP, the Committee notes that medical conditions affecting the permeability of the gut may be of particular importance in any safety consideration. So while the SCF did agree in 1983 that the use of carrageenan was acceptable at levels up to 0.3 g/l in follow-up milks which may be given from 4 months of age onwards,<sup>7</sup> it has more recently stated<sup>8</sup> that it wishes to defer its opinion on the use of carrageenan in weaning foods and may wish to reconsider its earlier opinion on follow-on formulae in the light of the ongoing review mentioned above.

*Conclusion* : The Committee is unable to offer an opinion on the acceptability of the use of carrageenan in FSMP until its current review on carrageenan is completed.

## **Guar gum (E412)**

Guar gum has been requested for use in FSMP at levels up to 10g/l from birth and 20g/l from 6 months of age in ready-to-use liquid formulae which contain extensively hydrolysed protein and/or amino acids, and for use at levels up to 1g/l in ready-to-use liquid formulae containing extensively hydrolysed proteins used from birth for infants in good health. In these products it acts to increase viscosity, delaying fat separation and so giving a longer shelf life. The FSMP are intended for children with intractable diarrhoea, other malabsorption conditions, impairment of the gastro-intestinal tract, protein intolerance or inborn errors of metabolism.

Guar gum has a JECFA ADI "not specified".<sup>34</sup> The SCF has already agreed that the use of guar gum is acceptable at levels up to 1 g/l in follow-up milks which may be given from 4 months of age onwards<sup>7</sup> and at levels up to 10g/kg in all weaning foods and up to 20g/kg in gluten-free, cereal-based weaning foods.<sup>13</sup> These uses are all included in Annex VI of Directive 95/2/EC.<sup>1</sup> In its 1994 opinion on infant formulae, the SCF reserved its view pending confirmation by industry of essential need and also noted that no multi-generation study was available.<sup>8</sup> The Committee further notes now that guar gum contains a significant protein fraction and that true allergy to guar gum via inhalation and subsequently the oral route has been recorded in exposed workers. The Committee therefore considers that guar gum is not suitable for use in liquid formulae for any age group in infants and young children suffering from protein intolerance, unless it can be shown that the products concerned comply with the conditions set out for products claiming reduced allergenic properties in Annex IV of Directive 91/321/EC<sup>9</sup> as amended by Commission Directive 96/4/EC.<sup>56</sup>

*Conclusion* : Guar gum is acceptable for use in FSMP from birth onwards, at levels up to 10g/l in ready-to-use liquid formulae which contain extensively hydrolysed protein and/or amino acids, and at levels up to 1g/l in ready-to-use liquid formulae containing partially hydrolysed proteins for infants in good health, provided that in the case of products intended for infants and young children with protein intolerance, the addition of guar gum does not jeopardise



compliance with the conditions set out for products claiming reduced allergenic properties in Annex IV of Directive 91/321/EC<sup>9</sup> as amended by Commission Directive 96/4/EC.<sup>56</sup> The Committee requires further technical justification for the need to use amounts higher than 10g/l in FSMP and in the meantime no more than 10g/l should be used.

## **Xanthan gum (E415)**

Xanthan gum has been requested for use in FSMP at levels up to 1.2 g/l in products based on amino acids and peptides given from birth onwards.<sup>2</sup> The Committee has been informed <sup>2</sup> that in these products, some of which are fed by tube, it acts in combination with guar gum to prevent sedimentation of components with low water solubility, such as fibre. The products concerned are for children with impairment of the gastrointestinal tract, protein malabsorption or inborn errors of metabolism.

The SCF changed its ADI of 10mg/kg b.w. set in 1978<sup>33</sup> to an ADI "not specified" in 1989.<sup>41</sup> This was based on lack of toxicity in animal feeding studies and observations in man and the then proposed levels of use (1-5g /kg in foods and 0.5 g/l in beverages). The SCF has also agreed that the use of xanthan gum is acceptable at levels up to 10g/kg in all weaning foods and up to 20g/kg in gluten-free, cereal-based weaning foods<sup>13</sup> and these uses are all included in Annex VI of Directive 95/2/EC.<sup>1</sup> It has a JECFA ADI "not specified".<sup>34</sup> There are no reasons to indicate it is unsuitable for infants from birth onwards.

*Conclusion* : The Committee considers that xanthan gum is acceptable for use at levels up to 1.2 g/l in FSMP.

## **Pectin (440)**

Pectin has been requested for use in FSMP in liquid and dry formulae at levels up to 10g/l in ready to feed form for products given from birth onwards for those with diarrhoea resulting from gastrointestinal disorders.<sup>2</sup> The Committee has been informed<sup>2</sup> that in these products it acts both as a gelling/thickening agent to delay gastric emptying and serves a physiological function as soluble dietary fibre.

The SCF has already agreed that the use of pectin is acceptable at levels up to 10g/kg in all weaning foods and up to 20g/kg in gluten-free, cereal-based weaning foods<sup>13</sup> and is acceptable in follow-on formulae up to 5g/l.<sup>8</sup> These uses are all included in Annex VI of Directive 95/2/EC.<sup>1</sup> In its opinion on infant formulae where the level of addition requested was 1g/l, the SCF has reserved its view pending confirmation by industry of essential need.<sup>8</sup> The SCF has endorsed<sup>33</sup> the JECFA ADI "not specified"<sup>10</sup> and there are no reasons to indicate it is unsuitable for infants from birth onwards.

*Conclusion* : The Committee considers that pectin is acceptable for use at levels up to 10g/l in FSMP.

## **Sodium carboxy methyl cellulose (E466)**

Sodium carboxy methyl cellulose has been requested for use in FSMP at levels up to 10g/l in liquid foods given from birth onwards and at levels up to 10g/kg in solid foods. These products are intended for metabolic disorders, such as inborn errors of fatty acid metabolism.<sup>2</sup> The Committee has been informed<sup>2</sup> that it acts as a thickening, gelling and solvation agent resulting in a less "sandy" mouth feeling.

The SCF has allocated an ADI "not specified" for modified celluloses as a group which included E466.<sup>42</sup> The Committee earlier reserved its opinion on a request to use E466 in weaning foods pending completion of its work on persorption of macromolecular additives but noted that otherwise the toxicological data did not indicate any effects likely to be of concern for infants and young children over weaning age.<sup>8</sup> However, the Committee has since been informed that sodium carboxy methyl cellulose in water is in colloidal form and hence is not likely to be persorbed.

*Conclusion* : The Committee considers that use of sodium carboxy methyl cellulose is acceptable in FSMP at levels up to 10g/l in liquid foods and at levels up to 10g/kg in solid foods.

## Glycerol (E422)

The use of glycerol at quantum satis levels has been requested as a non-cariogenic substitute for sugar as a sweetener in concentrated juices based on vegetables and fruits, especially intended for young children. Proposed levels are 5-15% in ready-to-drink product. Glycerol would also play a role as a preservative and as a solvent in such drinks.<sup>5</sup>

Sweeteners are regulated under Directive 94/35/EC and glycerol is not included in the list of permitted sweeteners.<sup>43</sup> Moreover, Article 2.3 of 94/35/EC states that sweeteners shall not be used in foods intended for infants or young children. Other low-calorie sweeteners, such as polyols, are not permitted in food for children under 3 years of age. The use of food additives in fruit juice in general is also restricted under Directive 95/2/EC, Annex II.1

JECFA allocated an ADI not specified in 1976, based on the daily intake of glycerol arising from its use, at the levels necessary to achieve the desired effect.<sup>44</sup> The SCF agreed with this view and considered glycerol acceptable for use as a solvent in food.<sup>45</sup>

Glycerol is rapidly absorbed after ingestion and readily metabolised. It can be converted to fat, shunted into glucose or glycogen synthesis or broken down by glycerokinase in the liver to carbon dioxide and water. Glycerol is reabsorbed in proximal tubuli, and is thus not normally present in urine. However, in the case of a glycerol overload it appears in the urine.<sup>46</sup>

Due to its pharmaceutical uses, the adverse effects of glycerol in humans have been studied. They are primarily due to its dehydrating action. The major effects of oral glycerol in otherwise healthy patients are headache, nausea and vomiting.<sup>47</sup> Less frequently diarrhoea, thirst, dizziness, and mental confusion can occur. Cardiac arrhythmias have also been reported. Mild osmotic diuresis occurs after oral glycerol doses of 1.0-1.3g glycerol/kg b.w.<sup>46</sup>

Following oral administration of 0.75-1.5g/kg b.w. in a 50%-75% solution, a relatively rapid increase in serum osmolality occurs, leading to a reduction of intraocular and intracranial pressure.<sup>48,49</sup> This dose level is used as treatment for acute glaucoma in children as well as adults. The effect on intraocular pressure may last for 4 to 10 hours.<sup>48</sup> Thirty minutes after ingestion of glycerol at a dose of 1g/kg b.w. the intracranial pressure was 4 times lower than before glycerol administration, and normalized after 4 hours.<sup>50</sup>

Medical specialists recommend that glycerol should be used cautiously in diabetic patients.<sup>47,49</sup> The absorption of glycerol is insulin-independent.<sup>51</sup> In an insulin-deficient organism glycerol is converted to glucose. Two-thirds of this glucose is metabolised in the Krebs's cycle and the remaining one third is released into the circulation. Glycerol administered orally increases the blood glucose level slightly in diabetic and minimally in non-diabetic patients. In addition, when glycerol is substituted as energy equivalent for glucose, it may reduce the blood glucose level and cause hypoglycaemia in diabetics receiving insulin.<sup>52</sup> An insulin-dependent man was given 120ml of 50% glycerol-solution (i.e. 0.9 g glycerol/kg b.w.) twice during 24 hours as treatment for neovascular glaucoma.<sup>51</sup> The patient developed hyperosmolar nonketonic coma due to dehydration. Since potassium deficiency may accompany diuresis it is also advised that individuals with congestive heart disease, hepatic or renal disorders should be monitored carefully when exposed to glycerol.

The proposed level of addition of glycerol is 5-15% in ready-to-drink product. At the higher level of addition, a child three years of age, weighing 15kg, and drinking 200ml juice would ingest 2g glycerol/kg b.w. Thus the amount of glycerol that might be consumed from the proposed use is comparable to the doses used when treating acute glaucoma. The juice concentrate would contain 65g glycerol/100ml according to the applicant.<sup>5</sup> A three year old child ingesting one to two tablespoonfuls of juice concentrate would be exposed to about 1g glycerol/kg b.w.

*Conclusion:* The adverse effects reported in non-diabetic patients occur at oral exposure levels which are similar to those which could be consumed as a result of the proposed concentrations in ready-to-drink products. The safety margin, if any, is small compared to exposure levels where the dehydrating effects of glycerol are apparent. In addition, oral glycerol at these intakes in combination with diabetes may have severe consequences. Since low-sugar products are often selected by patients with diabetes, its proposed use seems particularly undesirable. The reported mild diuretic effect of glycerol might also worsen the condition of a child already dehydrated by infection or other diseases. The

Committee considers that the use of glycerol is not acceptable in juices intended for young children.

### **Sodium-L-ascorbate E301**

Sodium-L-ascorbate has been requested for use as an antioxidant in coatings of nutrient preparations containing poly-unsaturated fatty acids which are used in infant formula and follow-on formula for infants and young children in good health and in FSMP for the same age group. The amounts used would give levels up to 75mg/l (expressed as ascorbic acid) in final foods.<sup>5,53</sup> The maximum level of addition requested is the same as that already permitted for addition of sodium-L-ascorbate as a dietetic additive to infant formulae and follow-on formulae. It is already permitted in certain weaning foods up to 0.3g/kg under Directive 95/2/EC.<sup>1</sup>

*Conclusion* : The Committee considers sodium-L-ascorbate to be acceptable as an antioxidant in coatings of nutrient preparations containing poly-unsaturated fatty acids in infant formula and follow-on formula for infants and young children in good health and in FSMP for the same age group, provided total levels in final food do not exceed 75mg/l.

### **L-ascorbyl palmitate E304**

L-ascorbyl palmitate has been requested as an antioxidant, for use in combination with tocopherols, at up to 10mg/l in infant formula and follow-on formula for infants and young children in good health and at corresponding levels in FSMP for the same age group.<sup>2</sup> It is already permitted in certain weaning foods up to 0.1g/kg under Directive 95/2/EC.<sup>1</sup> The Committee has previously examined the use of L-ascorbyl palmitate in the context of approved nutritional substances and technological additives 7,13.

*Conclusion* : The Committee considers L-ascorbyl palmitate to be acceptable as an antioxidant up to 10mg/l in infant formula and follow-on formula for infants and young children in good health and at corresponding levels in FSMP for the same age group.

### **Calcium citrate E333**

Calcium citrate has been requested at quantum satis levels for use as a firming agent in fruit-based products with a low sugar content in which low ester pectins have to be used, for infants and young children in good health. The Committee has been informed that addition of extra calcium ions achieves proper gel formation with low ester pectins. Calcium citrate dissolves slowly in the product donating calcium ions and is preferable to other, more rapidly dissolving calcium salts. The actual use level would depend on the calcium present in the fruit and could range from 100-1000mg/kg of product, corresponding to 1-0.25mg added Ca/g added pectin.<sup>5</sup> Calcium citrate is already permitted at quantum satis levels as a pH adjuster in weaning foods under Directive 95/2/EC.<sup>1</sup> It is also allowed as a source of nutrients in cereal based weaning food and baby foods under Directive 96/5/EC.<sup>54</sup>

*Conclusion* : The Committee considers the use of calcium citrate in fruit-based baby foods with a low sugar content is acceptable provided the amounts added do not exceed the maximum limit for calcium for this category of foods set out in Article 5 of 96/5/EC.<sup>54</sup>

### **Tricalcium phosphate E341**

Tricalcium phosphate has been requested as a firming agent for use in combination with pectin to improve gel formation in fruit desserts for infants and young children in good health.<sup>4</sup> Calcium salts of orthophosphoric acid are permitted sources of nutrients in weaning foods under Directive 91/321/EEC<sup>9,13</sup> and in cereal foods and baby foods under Directive 96/5/EC.<sup>54</sup> It is also permitted as an additive in weaning foods up to 1g/kg (expressed as P<sub>2</sub>O<sub>5</sub>), either singly or in combination with other phosphates, under Directive 95/2/EC.<sup>1</sup>

*Conclusion* : The Committee considers that the use of tricalcium phosphate up to a maximum level of 1g/kg is acceptable as a firming agent in fruit desserts for infants and young children in good health.

## Acacia gum (E414)

Acacia gum, also known as gum arabic, has been requested for use in nutrient preparations, up to a level of 150g/kg, as a coating for vitamins and trace elements added to infant formula and follow-on formula for infants and young children in good health and for FSMP for the same age group.<sup>2</sup> It is required in the coating to prevent oxidation of the vitamins and in the case of certain trace elements to prevent them causing peroxidation of unsaturated fatty acids with which they may come in contact.<sup>2</sup> The Committee has already considered the use of acacia gum/gum arabic in coatings for vitamin preparations and concluded that use resulting in a low level of carry over of 10mg/kg in infant formula, follow-on formula and weaning foods was acceptable.<sup>55</sup> The same level of addition to the coating of trace elements has been requested as was previously requested for the coating of vitamins (150 g/kg of nutrient preparation). Acacia gum is currently permitted as a direct additive in weaning foods up to 10mg/kg and in gluten-free, cereal based foods up to 20mg/kg.<sup>9,1</sup>

*Conclusion* : The Committee considers that the use of acacia gum/gum arabic in coatings for nutrient preparations containing trace elements is acceptable provided carry over levels in infant formula, follow-on formula or FSMP do not exceed 10mg/kg.

## Discussion

IDACE proposed that the additives requested be considered according to three categories of product, that is, those which may be used from birth, those from the age of 6 months and those from the age of one year, reflecting the current market. FSMPs can be introduced into the diet of infants, alone or in association with other foods from the first days of life. The Committee has considered each additive requested for use in FSMP from the health point of view in relation to whether their use is justified in the particular circumstances of feeding infants and young children suffering from particular medical conditions, taking due account of the immaturity of physiological systems in the very young infant, especially in those below 12 weeks of age. For example, since protein hydrolysates may have to be used from birth, there should be no age restriction on the use of acceptable emulsifiers with respect to infants who may be given them. Similarly the Committee sees no reason to make a special distinction at 6 months of age instead of 4 months of age. According to Council Directive 91/321/EC, "infants" means those below 12 months of age and "young children" those between 12 and 36 months of age.<sup>9</sup>

FSMP are intended for use for a very heterogeneous group of medical conditions and it should be noted that the views on safety which the Committee offers in this opinion can only be based on general considerations rather than considerations of the precise nature of the various illnesses and conditions for which they are intended for use.

Since the required levels of addition of emulsifiers in FSMP may be relatively high for some products, the Committee has given careful consideration to whether it would be possible to regularly exceed the ADI for any of the additives requested, in cases where a numerical ADI has been allocated. This does not appear to be the case.

## Conclusions and recommendations

The Committee's recommendations have been reached after consideration of each request with respect to case of need, safety and nutritional requirements, bearing in mind the need to keep the number of additives in foods for infants and young children, whether sick or in good health, to the minimum necessary. In the case of additives requested for use from birth onwards, the Committee was particularly conscious of the physiological situation in infants and very young children. The Committee draws attention to the fact that in some countries, products made with hydrolysed proteins for infants and young children with protein intolerance are not marketed as FSMPs but as products for infants and young children in good health.

The Committee's recommendations on the requested additives are summarised in the table below. The opinion on acceptability applies only to the uses and the maximum levels of use specified. It should be noted that in cases where the Committee has recommended that the use of an additive in FSMP is acceptable, this does not imply that its use in

foods for infants and young children in good health is also acceptable, unless so stated. Equally, a recommendation that an additive is acceptable for use in foods for infants and young children in good health does not necessarily imply that it is acceptable in FSMPs. It follows that should the recommendations in the present opinion be implemented in due course by amendment of Directive 95/2/EC, this may require a change in the wording of Part 4 of Annex VI to the Directive, which currently permits all additives for infants and children in good health to be used in FSMP.

## Summary of recommendations

Additive	Requested Products & Maximum Level of Use	Opinion: foods for infants and young children in good health	Opinion: FSMPs for infants and young children
Sodium-L-ascorbate E301 (Page 15)	In coatings of NP containing PUFA added to IF, FOF, FSMP. Level not to exceed 75mg/l (expressed as ascorbic acid) in final foods	Acceptable from birth onwards for the requested conditions of use	Acceptable from birth onwards for the requested conditions of use
L-ascorbyl palmitate E304 (Page 16)	IF, FOF 10 mg/l, FSMP at same levels	Acceptable from birth onwards for the requested conditions of use	Acceptable from birth onwards for the requested conditions of use
Sodium citrate E331 (Page 5)	IF, FOF, FSMP 2g/kg	Acceptable from birth onwards for the requested conditions of use	Acceptable from birth onwards for the requested conditions of use
Potassium citrate E332 (Page 5)	IF, FOF, FSMP 2g/kg	Acceptable from birth onwards  for the requested conditions of use	Acceptable from birth onwards for the requested conditions of use
Calcium citrate E333 (Page 16)	WF  Quantum satis in low-sugar fruit-based products	Acceptable up to limit for Ca in 96/5/EC  for the requested conditions of use	N/R
Sodium phosphate E339(Page 6)	IF, FOF, FSMP  1g/l expressed as P2O5, provided Ca:P ratio within limits in 91/321/EEC	Acceptable from birth onwards for the requested conditions of use	Acceptable from birth onwards for the requested conditions of use
Potassium phosphate E340 (Page 6)	IF, FOF, FSMP  1g/l expressed as P2O5, provided Ca:P ratio within limits in 91/321/EEC	Acceptable from birth for the requested conditions of use	Acceptable from birth onwards for the requested conditions of use
Tricalcium phosphate E341	WF  1g/kg in fruit-based desserts	Acceptable for the requested conditions of use	N/R

<b>Additive</b>	<b>Requested Products &amp; Maximum Level of Use</b>	<b>Opinion: foods for infants and young children in good health</b>	<b>Opinion: FSMP for infants and young children</b>
Sodium alginate E401 (Page 10)	FSMP 1g/l	N/R	Acceptable from 4 months onwards for the requested conditions of use
Propane-1,2-diol alginate E405 (Page 11)	FSMP 0.2g/l	N/R	Acceptable from 12 months onwards for the requested conditions of use
Carrageenan E407 (Page 11)	FSMP 300 mg/l	N/R	Opinion deferred; not acceptable in the meantime
Locust bean gum E410 (Page 7)	IF, FOF, FSMP 10g/l in products for reduction of gastro-oesophageal reflux	Not acceptable	Acceptable from birth onwards for the requested conditions of use
Guar gum E412 (Page 12)	IF, FOF 1g/l FSMP 10g/l in liquid formulae containing hydrolysed proteins, peptides or amino acids, 20g/l from 6 months of age	Acceptable from birth onwards for the requested conditions of use provided infant formulae comply with conditions in Annex IV of 91/321/EEC as amended by 96/4/EC	Acceptable from birth onwards for the requested conditions of use up to 10g/l. (20 g/l not acceptable pending technical justification)
Acacia gum E414 (Page 17)	In coatings of NP containing vitamins and trace elements added to IF, FOF and FSMP. 150g/kg in NP, carry-over level not to exceed 10mg/kg	Acceptable from birth onwards for the requested conditions of use	Acceptable from birth onwards for the requested conditions of use
Xanthan gum E415 (Page 13)	FSMP 1.2g/l	N/R	Acceptable from birth onwards for the requested conditions of use
Glycerol E422 (Page 14)	WF Quantum satis in concentrated juices based on vegetables and fruits	Not acceptable	N/R

<b>Additive</b>	<b>Requested Products &amp; Maximum Level of Use</b>	<b>Opinion: foods for infants and young children in good health</b>	<b>Opinion: FSMP for infants and young children</b>
Pectin E440 (Page 13)	FSMP	N/R	Acceptable from birth onwards for the requested

	10g/l		conditions of use
Sodium carboxymethyl cellulose E466 (Page 13)	FSMP 10g/l (liquid) 10g/kg (solid)	N/R	Acceptable from birth onwards for the requested conditions of use
Mono- & di-glycerides of fatty acids E471 (Page 8)	FSMP 5g/l	N/R	Acceptable from birth onwards for the requested conditions of use
Citric acid esters of mono- & di-glycerides of fatty acids E472c (Page 8)	IF, FOF, FSMP 7.5 g/l (dry) 9g/l (liquid) containing hydrolysed proteins, peptides or amino acids	Acceptable from birth onwards for the requested conditions of use	Acceptable from birth onwards for the requested conditions of use
Diacetyl tartaric acid esters of mono- & di-glycerides of fatty acids E472e (Page 9)	IF, FOF, FSMP containing hydrolysed proteins, peptides or amino acids, 0.4 g/l (as consumed). WF 5g/l in gluten-free bakery products for coeliac patients	Opinion deferred; not acceptable in the meantime	Temporarily acceptable from birth onwards for the requested conditions of use
Sucrose esters of fatty acids E473 (Page 10)	IF, FOF, FSMP containing hydrolysed proteins, peptides or amino acids, 120mg/L	Acceptable from birth onwards for the requested conditions of use	Acceptable from birth onwards for the requested conditions of use
Distarch phosphate E1412 (Page 4)	IF, FOF, FSMP 10g/l (dry) 22g/l (liquid)	Opinion deferred; not acceptable in the meantime	Opinion deferred pending submission of case of need; not acceptable in the meantime

### ***Key to summary table***

IF = Infant Formula } for infants and young  
FOF = Follow-On Formula } children in  
WF = Weaning Foods } good health  
FSMP = Foods for Special Medical Purposes  
NP = Nutrient Preparations  
N/R = Not Requested  
PUFA = Poly-Unsaturated Fatty Acids

### **References**

1. European Parliament and Council Directive 95/2/EC of 20 February 1995 on food additives other than colours and sweeteners. Official Journal of the European Communities No L61/1-40, 18.3.95.
2. Requests and supporting technological justifications for amendments to the European Parliament and Council Directive 95/2/EC of 20 February 1995 on Food Additives Other Than Colours and Sweeteners. CS/ADD/MsAd/126, May 1995. Unpublished submission to the Scientific Committee for Food by IDACE, Paris.
3. FSMPs other than colours and sweeteners: additional information on emulsifiers. CS/ADD/MsAd/149, September 1996. Unpublished submission to the Scientific Committee for Food by Scientific Hospital Supplies International, Liverpool.
4. Additives for use in foods for infants and young children: Background information to IDACE submission.

- CS/ADD/MsAd/142, July 1996. Unpublished submission to the Scientific Committee for Food by IDACE, Paris.
5. Additives for use in foods for infants and young children: Glycerol in fruit and vegetable based drinks for young children (E422); calcium citrate as a firming agent in low sugar-based drinks for young children (E333); sodium-L-ascorbate as an antioxidant in coatings of nutrient preparations containing poly-unsaturated fatty acids (E301). CS/ADD/MsAd/138, May 1996. Unpublished submission to the Scientific Committee for Food by IDACE, Paris.
  6. Commission of the European Communities (1997). Opinion on Colours in Foods for Special Medical Purposes for Young Children (expressed on 13 December 1996). CS/ADD/COL/134-Final. Annex VI to Minutes of the 105th Meeting of the Scientific Committee for Food Held on 12-13 December 1996 in Brussels. Document III/5156/97. CEC, Brussels.
  7. Commission of the European Communities (1983). First Report of the Scientific Committee for Food on the Essential Requirements of Infant Formulae and Follow-up Milks Based on Cows' Milk Proteins. Reports of the Scientific Committee for Food (Fourteenth Series). CEC, Luxembourg.
  8. Commission of the European Communities (1994). Opinion on Certain Additives for Use in Infant Formulae, Follow-on Formulae and Weaning Foods. Reports of the Scientific Committee for Food. (Thirty-second series). CEC, Luxembourg.
  9. Commission Directive 91/321/EEC on Infant Formulae and Follow-on Formulae. Official Journal of the European Communities No L175/35-49, 4.7.91.
  10. Joint FAO/WHO Expert Committee on Food Additives (1974). Toxicological evaluation of some food additives including anticaking agents, antimicrobials, antioxidants, emulsifiers and thickening agents. WHO Food Additives Series No 5. WHO, Geneva.
  11. Commission of the European Communities (1982). Second Report of the Scientific Committee for Food on Modified Starches. Reports of the Scientific Committee for Food (Thirteenth Series). CEC, Luxembourg.
  12. Joint FAO/WHO Expert Committee on Food Additives (1982). Toxicological evaluation of certain food additives. WHO Food Additives Series No 17. WHO, Geneva.
  13. Commission of the European Communities (1991). First Report of the Scientific Committee for Food on the Essential Requirements for Weaning Foods. Reports of the Scientific Committee for Food (Twenty-fourth Series). CEC, Luxembourg.
  14. Lebenthal E and Schwachman H (1977). The pancreas development, adaptation and malfunction in infancy and childhood. *Clinical Gastroenterology* 6, 397-413.
  15. Shulman R J, Kerzner B, Sloan H R, Boutton T W, Wong W W, Buford L N and Klein P D (1986). Absorption and oxidation of glucose polymers of different lengths in young infants. *Pediatric Research* 20, 740-743.
  16. De Visia B, Ciccimarra F, DeCicco N and Auricchio S (1975). Digestibility of starches in infants and children. *Journal of Pediatrics* 86, 50-55.
  17. Lilibridge C B and Townes P L (1973). Physiological deficiency of pancreatic amylase in infancy: a factor in iatrogenic diarrhoea. *Journal of Pediatrics* 82, 279-282.
  18. Lee P C, Brooks S P, Kim O, Heitlinger L A and Lebenthal E (1985). Digestibility of native and modified starches: in vitro studies with human and rabbit pancreatic amylases and in vivo studies in rabbits. *Journal of Nutrition* 115, 93-103.
  19. Sevenhuysen G P, Holodinsky C and Dawes C (1984). Development of salivary alpha-amylase in infants from birth to 5 months. *American Journal of Clinical Nutrition* 39, 584-588.
  20. Mizrahi A, London RD and Gribetz D (1968). Neonatal hypocalcaemia - its causes and treatment. *New England Journal of Medicine* 278, 1163-1165.
  21. National Research Council (1989). Recommended Dietary Allowances. 10th edition, National Academy Press, Washington DC.
  22. Hofvander Y, Hagman U, Hillervik C and Sjölin S (1982). The amount of milk consumed by 1-3 months old breast- or bottle-fed infants. *Acta Paediatrica Scandinavica* 71, 953-958.
  23. Vandenplas Y, Ashkenazi A, Belli D, Boige N, Bouquet J, Cadranet S et al (1993). A proposition for the diagnosis and treatment of gastro-oesophageal disease in children: a report from a working group on gastro-oesophageal reflux disease. *European Journal of Paediatrics* 152, 704-711.
  24. Bailey DJ, Andres JM, Danek GD and Pineiro-Carrero VM (1987). Lack of efficiency of thickened feeding as a treatment for gastroesophageal reflux. *Journal of Pediatrics* 110, 187-189.
  25. Vandenplas Y and Sacré L (1987). Milk-thickening agents as a treatment for gastro-oesophageal reflux. *Clinical Pediatrics* 26, 66-68.
  26. Vandenplas Y (1993). The diagnosis and treatment of gastro-oesophageal reflux disease in infants and children.



- Annals of Medicine 25, 323-328.
27. Davies AEM and Sandhu BK (1995). Diagnosis and treatment of gastro-oesophageal reflux. Archives of Diseases of Childhood 73, 82-86.
  28. Orenstein S, Shalaby TM and Putnam PE (1992). Thickened feedings as a cause of increased coughing when used as therapy for gastroesophageal reflux in infants. Journal of Pediatrics 121, 913-915.
  29. Joint FAO/WHO Expert Committee on Food Additives (1981). Twenty-fifth report of the Joint FAO/WHO Expert Committee on Food Additives. WHO Food Additives Series No 16. WHO, Geneva.
  30. Vohra P, Shariff G and Kratzer FH (1979). Growth inhibitory effect of some gums and pectin for *Tribolium castaneum* larvae, chickens and Japanese quail. Nutrition Reports International 19, 463-469.
  31. National Research Council (1989). Diet and Health: Implications for Reducing Chronic Disease Risk. National Academy Press, Washington DC, pp291-309.
  32. EEC Directive 74/329/EEC of 18 June 1974 on Emulsifiers, Stabilisers, Thickening and Gelling Agents for use in Foodstuffs. Official Journal of the European Communities, L189, p1, 12.7.74.
  33. Commission of the European Communities (1978). Report of the Scientific Committee for Food on Emulsifiers, Stabilisers, Thickening and Gelling Agents. Reports of the Scientific Committee for Food (Seventh Series). CEC, Luxembourg.
  34. World Health Organisation (1974). Toxicological evaluation of certain food additives with a review of general principles and of specifications. Seventeenth Report of the joint FAO/WHO Expert Committee on Food Additives. WHO Technical Report Series No. 539. WHO, Geneva.
  35. Council Directive 89/398/EEC on foods for particular nutritional uses, Official Journal of the European Communities No L 186/27-32, 30.6.89
  36. Commission of the European Communities (1992). Sucroglycerides and sucrose esters. Minutes of the 83rd Meeting of the Scientific Committee for Food held on 10 April 1992 in Brussels. Document III/3280/92, CEC DG III, Brussels.
  37. World Health Organisation (1995). Evaluation of certain food additives and contaminants. Forty-fourth Report of the Joint FAO/WHO Expert Committee on Food Additives. WHO Technical Report Series No. 859. WHO, Geneva.
  38. World Health Organisation (1992). Evaluation of certain food additives and contaminants. Thirty-ninth Report of the Joint FAO/WHO Expert Committee on Food Additives. WHO Technical Report Series No. 828. WHO, Geneva.
  39. Commission of the European Communities (1990). Alginates. Minutes of the 75th Meeting of the Scientific Committee for Food held on 17-19 October 1990 in Berlin. Document III/9212/90, CEC DG III, Brussels.
  40. World Health Organisation (1993). Evaluation of certain food additives and contaminants. Forty-first Report of the Joint FAO/WHO Expert Committee on Food Additives. WHO Technical Report Series No. 837. WHO, Geneva.
  41. Commission of the European Communities (1992). Report of the Scientific Committee for Food on a Second Series of Food Additives of Various Technological Functions. Reports of the Scientific Committee for Food (Twenty-sixth Series). CEC, Luxembourg.
  42. Commission of the European Communities (1996). Opinion on cross-linked sodium carboxymethylcellulose (modified cellulose gum). Reports of the Scientific Committee for Food, Thirty-fifth Series. CEC, Luxembourg.
  43. European Parliament and Council Directive 94/35/EC of 30 June 1994 on sweeteners for use in foodstuffs. Official Journal of the European Communities No L237/3-12, 10.9.94.
  44. Joint FAO/WHO Expert Committee on Food Additives (1976). Toxicological evaluation of certain food additives. WHO Food Additives Series No 10. WHO, Geneva.
  45. Commission of the European Communities (1981). Report of the Scientific Committee for Food on Extraction Solvents. Reports of the Scientific Committee for Food (Eleventh Series). CEC, Luxembourg.
  46. McCurdy DK, Schneider B and Sheie HG (1966). Oral glycerol: The mechanism of intraocular hypotension. American Journal of Ophthalmology 61, 1244-1249.
  47. Martindale : The Extra Pharmacopoeia (1996). Thirty-first edition. Ed: JEF Reynolds. Royal Pharmaceutical Society. London.
  48. Kwitko ML (1981). The pediatric glaucomas. International Ophthalmology Clinics 21, 199-222.
  49. Bartlett JD (1991). Adverse effects of antiglaucoma medications. Optometry Clinics 1, 103-126.
  50. Kugler KK, Dick AR and Nelson SR (1977). Intraocular and intraventricular pressures after glycerol ingestion. Archives of Neurology 34, 451.

51. Oakley DE and Ellis PP (1976). Glycerol and hyperosmolar nonketonic coma. *American Journal of Ophthalmology* **81**, 469-472.
52. Freund G (1968). The metabolic effects of glycerol administered to diabetic patients. *Archives of Internal Medicine* **121**, 123.
53. Additional Information on sodium-L-ascorbate. CS/ADD/MsAd/155, December 1996. Unpublished submission to the Scientific Committee for Food by IDACE, Paris.
54. Commission Directive 96/5/EC on cereal based foods and baby foods. *Official Journal of the European Communities* No L 49/17-28, 28.2.96.
55. Commission of the European Communities (1996). Opinion on additives in nutrient preparations for use in infant formulae, follow-on formulae and weaning foods. Minutes of the 103rd Meeting of the Scientific Committee for Food held on 19-20 September. Annex IV to Document III/5693/96. CEC DGIII, Brussels.
56. Commission Directive 96/4/EC of 16 February 1996 amending Directive 91/321/EEC on infant formulae and follow-on formulae. *Official Journal of the European Communities* No L 49/12-16, 28.2.96.
57. Commission of the European Communities (1997). Opinion of the Scientific Committee for Food on diacetyltartaric acid esters of mono- and diglycerides (DATEM E472e), expressed on 13 June 1997. Minutes of the 107th meeting of the Scientific Committee for Food, 12-13 June 1997.