

## Supporting document 2

### Food Technology Assessment – Proposal P242 (Final Assessment)

#### Food for Special Medical Purposes

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## Executive summary

### Assessment of food additives and processing aids

At preliminary final assessment, FSANZ proposed to include an entry for FSMP in Schedule 1 of Standard 1.3.1. Unless otherwise specified in Schedule 1 of Standard 1.3.1, food additives in Schedules 2, 3 and 4 may be added to processed foods in accordance with GMP. FSANZ concluded that as FSMP are processed foods containing a number of food ingredients, permission for the use of Schedule 2, 3 and 4 food additives was technologically justified.

In the December 2010 Consultation Paper, when the project recommenced, FSANZ proposed to include an entry for FSMP in Schedule 1 of Standard 1.3.1 – Food Additives that permitted:

- the addition of food additives listed under Schedules 2 and 3 of Standard 1.3.1 to FSMP
- an additional eleven food additives (four sorbates, four benzoates, acesulphame potassium, aspartame-acesulphame salt, and saccharin) with associated maximum levels for their use in FSMP.

The FSMP industry has indicated in submissions to the Consultation Paper, and in subsequent consultations with FSANZ, that additional permissions are required for colour additives as listed in Schedule 4 of Standard 1.3.1, the colours amaranth and annatto, butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), phosphoric acid, sodium hydroxide and potassium hydroxide.

FSANZ assessed these additional requests and recommended that:

- Schedule 4 colours be permitted for addition to FSMP, as the use of these colours is technologically justified for FSMP and is consistent with EU food additive regulations.
- amaranth and annatto be permitted for addition to FSMP. Their addition to FSMP is technologically justified and they are already permitted in the Code for use in a variety of processed foods. Different maximum levels of use are required for liquid and non-liquid FSMP due to the differing applications of these colours.

- the carry-over provisions in clause 7 of Standard 1.3.1 are sufficient for the presence of BHA and BHT in FSMP and therefore specific permissions for FSMP are not required.
- phosphoric acid, sodium hydroxide and potassium hydroxide be permitted for addition to FSMP as acidity regulators. The use of these additives is technologically justified and they are generally permitted as processing aids in Standard 1.3.3 and as food additives in the European Union, United States of America and by Codex.

This food technology assessment recommends that sixteen food additives are determined as safe and technologically justified for use in FSMP. These food additives are in addition to the food additive permissions in Schedules 2, 3 and 4 of Standard 1.3.1 and the processing aid permissions in Standard 1.3.3.

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## **1. Introduction**

The use of food additives in foods in Australia and New Zealand is subject to the requirements of Standard 1.3.1 – Food Additives of the Code. Food additives are intentionally added to a food to achieve one or more technological functions (specified in Schedule 5 to Standard 1.3.1) in the final food. A food additive may only be added to food where expressly permitted in Standard 1.3.1 and in order to achieve an identified technological function according to Good Manufacturing Practice (GMP). Food additives are added to foods to assist in improving the quality, stability, taste, appearance, shelf life and safety of processed foods.

It is important to note that, in accordance with GMP, the amount of a food additive used in any food must not exceed the maximum level necessary to achieve the primary technological function. This also means that additives that are not needed must not be added. An approval to use a food additive does not mean that the food additive has to be used.

The use of processing aids in foods is subject to the requirements of Standard 1.3.3 – Processing Aids of the Code. Processing aids differ from food additives in so far as they perform a technological function during the processing of a food, but not in the final food. Processing aids are prohibited for use in foods unless there are explicit permissions in Standard 1.3.3.

There is currently no specific permission in Standard 1.3.1 for the addition of food additives to foods for special medical purposes (FSMP). At Preliminary Final Assessment, FSANZ proposed an approach to permit the use of some food additives in these foods. This approach is outlined in more detail below.

In early 2010, FSANZ consulted with the FSMP industry and asked whether the approach proposed at Preliminary Final Assessment would satisfactorily reflect the use of food additives in existing FSMP sold in Australia and New Zealand; the majority of which are sourced from overseas markets. The FSMP industry requested some additives be specifically permitted, in Standard 1.3.1, to be added to FSMP.

In this assessment, FSANZ has investigated the technological justification for the use of these food additives in FSMP and the potential for harmonisation with international regulations.

It is important to note that FSMP products have been available in the Australian and New Zealand markets in the absence of a standard for these products. Therefore, there is a history of use of these products in Australia and New Zealand.

In addition, the food additives included in this assessment are permitted in Standard 1.3.1 in other foods on the basis of previous FSANZ risk assessments. This food additive assessment has been conducted on the basis that there is a safe history of consumption of FSMP in Australia and New Zealand and that the food additives discussed below have undergone previous FSANZ and international risk assessment before being permitted for use in other foods. Therefore, FSANZ did not consider a separate safety assessment was required for the food additives included in this food technology assessment.

## **2. Key assessment questions**

The following questions apply to the food additives requested for addition to FSMP by the FSMP industry:

- a) Has the technological function in FSMP been articulated clearly for these food additives?
- b) Are these food additives safe for use in FSMP?
- c) Is there a need to establish maximum levels for the use of these food additives in FSMP, in order to protect public health and safety? If so, what should they be?

### **3. Assessment of food additives and processing aids**

The use of food additives in foods in Australia and New Zealand is subject to the requirements of Standard 1.3.1 – Food Additives of the Code. Food additives are intentionally added to a food to achieve one or more technological functions (specified in Schedule 5 to Standard 1.3.1) in the final food. A food additive may be added to food only where expressly permitted in Standard 1.3.1 and in order to achieve an identified technological function according to Good Manufacturing Practice (GMP). Food additives are added to foods to assist in maintaining the quality, taste and safety of processed foods.

It is important to note that, in accordance with GMP, the proportion of a food additive used in any food must not exceed the maximum level necessary to achieve the primary technological function. This also means that additives that are not needed must not be added. An approval to use a food additive does not mean that food additive has to be used.

The use of processing aids in foods is subject to the requirements of Standard 1.3.3 – Processing Aids of the Code. Processing aids differ from food additives in so far as they perform a technological function during the processing of a food, but not in the final food. Processing aids are prohibited for use in foods unless there are explicit permissions in Standard 1.3.3.

There is currently no specific permission in Standard 1.3.1 for the addition of food additives to FSMP. At Preliminary Final Assessment, FSANZ proposed an approach to permit the use of some food additives in these foods. This approach is outlined in more detail below.

FSANZ has recently consulted with the FSMP industry and asked whether the approach proposed at Preliminary Final Assessment would satisfactorily reflect the use of food additives in existing FSMP sold in Australia and New Zealand, noting that the majority are sourced from overseas markets.

In this assessment, FSANZ has investigated the technological justification for the use of these food additives in FSMP and the potential for harmonisation with international regulations.

#### **3.1 Previous considerations at December 2010**

At Preliminary Final Assessment, FSANZ proposed to include an entry for FSMP in Schedule 1 of Standard 1.3.1.

Unless otherwise specified in Schedule 1 of Standard 1.3.1, food additives in Schedules 2, 3 and 4 may be added to processed foods in accordance with GMP. FSANZ concluded that as FSMP are processed foods containing a number of food ingredients, permission for the use of Schedule 2, 3 and 4 food additives was technologically justified.

FSANZ noted that foods and ingredients used to prepare FSMP may also contain food additives (provided the foods and ingredients themselves are permitted to contain food additives) and that these food additives may therefore be present in the final FSMP. Clause 7 of Standard 1.3.1 – Carry-over of additives, provides for the presence of additives as a result of carry-over, provided that the level of the additive in the final food is no greater than would be introduced by the use of the ingredient under proper technological conditions and

GMP. For example, antioxidants permitted to be added to edible oils will be permitted to be present in individual FSMP by carry-over if an edible oil containing the antioxidants is used as an ingredient. Similarly, foods that contain the preservatives sorbates and benzoates can also be used as ingredients in FSMP, with similar carry-over permissions.

All Schedule 2 additives are also generally permitted processing aids (clause 3(b) of Standard 1.3.3 – Processing Aids). The FSMP industry is not expected to have any technological need for the use of processing aids outside the current permissions in Standard 1.3.3 – Processing Aids.

### 3.2 Food additives requested by industry for use in FSMP

The FSMP industry has identified food additives that, in their opinion, warrant specific permission for use in FSMP. These additives are present in some FSMP currently available on the Australian and New Zealand markets. The majority of these FSMP are manufactured overseas in accordance with overseas regulatory requirements and are imported into Australia and New Zealand. The FSMP industry has requested specific permission in Schedule 1 of Standard 1.3.1 for the additives listed in Table 1 below, in addition to the generally permitted food additives and in addition to the permission for the presence of these additives by carry-over in FSMP proposed by FSANZ at PFAR. Table 1 also includes the maximum permitted levels of use of these additives in this food type in the European Union (EU) and in the United States of America (USA).

The majority of the food additives in Table 1 are currently permitted in a range of foods in Standard 1.3.1. Two of the requested food additives (potassium hydroxide and sodium hydroxide) are not permitted in Schedule 1 of Standard 1.3.1, but are generally permitted processing aids in Standard 1.3.3 and are permitted as food additives in the EU, the USA and in the Codex General Standard for Food Additives (GSFA). The technological functions of these food additives are well established for use in the foods in which they are permitted.

In this assessment, FSANZ has considered whether specific permission to add these food additives to FSMP is justified. Where specific permission was considered to be warranted, FSANZ has also considered whether maximum levels of use also need to be established for each of the food additives.

**Table 1: Food additives specifically requested by the FSMP industry**

Additive (INS)	Maximum permitted level (mg/kg or mg/L)	
	Europe	United States of America
<b>Preservatives</b>		
Sorbic acid (200)	1500*	GMP
Sodium sorbate (201)	NP	GMP
Potassium sorbate (202)	1500*	GMP
Calcium sorbate(203)	1500*	GMP
Benzoic acid (210)	1500*	1000 (GRAS)
Sodium benzoate (211)	1500*	1000 (GRAS)
Potassium benzoate (212)	1500*	NP
Calcium benzoate (213)	1500*	NP
<b>Intense sweeteners</b>		
Acesulfame K (950)	450	GMP
Aspartame (951)	1000	GMP
Saccharin (and its Na, K, Ca salts) (954)	200	400 mg/L (12 mg/fluid ounce) for beverages, fruit juice drinks and bases or mixes 30mg per serve in processed foods
Aspartame-Acesulfame salt (962)	450	NP

Additive (INS)	Maximum permitted level (mg/kg or mg/L)	
	Europe	United States of America
<b>Antioxidants</b>		
Butylated hydroxyanisole (320)	NP	GRAS: 0.02% of fat or oil content
Butylated hydroxytoluene (321)	NP	GRAS: 0.02% of fat or oil content
<b>Colours</b>		
Annatto (160b)	GMP	GMP
Amaranth (123)	GMP	NP
<b>Acidity regulators</b>		
Phosphoric acid (338)	Various <sup>^</sup>	GMP
Sodium hydroxide (524)	GMP	GMP
Potassium hydroxide (525)	GMP	GMP

\* Maximum level applies to each additive used singly or in combination. If used in combination, there may be no more than 1500 mg/kg total sorbates and benzoates combined<sup>1</sup>.

<sup>^</sup> Levels up to 1000mg/kg.

NP – not permitted

### 3.3 Assessment of the addition of specific food additives to FSMP

The majority of FSMP in the Australian and New Zealand markets are imported and are generally manufactured to comply with EU or USA regulatory requirements. Recognising the importance of FSMP for the intended consumers in Australia and New Zealand, and that the majority of existing products are imported, FSANZ considers it appropriate to harmonise the requirements for food additive use in FSMP as much as possible with international requirements.

For each of the requested food additives, FSANZ has compared the existing permissions in Schedule 1 of Standard 1.3.1 for similar foods, including maximum permitted levels, with permissions and maximum levels in the EU and USA regulations. This comparison provides an indication of whether the overseas maximum levels are consistent with use levels already permitted in foods in Australia and New Zealand.

The comparisons and FSANZ conclusions for each of the requested food additives are given below.

#### 3.3.1 Preservatives

##### 3.3.1.1 Sorbates

Sorbic acid and sodium, potassium and calcium sorbates (referred to collectively as sorbates hereafter) are permitted in a wide variety of processed foods including cheese, dried fruits and vegetables, low joule jams and spreads, sugar confectionery, pasta, bread and baked products, dried meat, semi-preserved fish and fish products, liquid tabletop sweeteners, fruit juice, water-based flavoured drinks, dairy- and fat-based desserts and sauces, mayonnaise and salad dressings.

The maximum permitted levels for sorbates in Standard 1.3.1 in commonly consumed foods are consistent with the maximum levels of use in FSMP in the EU regulations (1500 mg/kg). The USA permits sorbates at levels consistent with good manufacturing practice rather than setting a maximum level.

<sup>1</sup> This concept is consistent with clause 6 of Standard 1.3.1 regarding maximum levels of additives performing the same technological functions in foods.

### *Conclusion*

FSANZ concludes that a maximum permitted level in Schedule 1 of Standard 1.3.1 of 1500 mg/kg of sorbates is appropriate for FSMP<sup>2</sup>.

#### **3.3.1.2 Benzoates**

Benzoic acid and sodium, potassium and calcium benzoates (referred to collectively as benzoates hereafter) are permitted in a wide variety of processed foods including oil emulsions, liquid ice confection, low joule jams and spreads, icings and frostings, semi-preserved fish and fish products, liquid tabletop sweeteners, sports foods, fruit and vegetable juices, water-based flavoured drinks, dairy- and fat-based desserts and sauces, mayonnaise and salad dressings.

The maximum permitted levels for benzoates in Standard 1.3.1 in commonly consumed foods are the same as the maximum levels of use in FSMP in the EU regulations (1500 mg/kg). Benzoic acid and sodium benzoate are generally recognised as safe (GRAS) in the USA at 0.1% (equivalent to 1000 mg/kg).

### *Conclusion*

FSANZ concludes that a maximum permitted level in Schedule 1 of Standard 1.3.1 of 1500 mg/kg of benzoates is appropriate for FSMP<sup>2</sup>.

#### **3.3.2 Intense sweeteners**

##### **3.3.2.1 Acesulfame-potassium**

Acesulfame-potassium is permitted, in Standard 1.3.1, in a wide variety of foods including liquid milk products, ice creams, fruit and vegetable spreads, confectionery, flour products (including pasta), biscuits, cakes, pastries, tabletop sweeteners, sports foods, meal replacements and supplementary foods, water-based flavoured drinks and mixed foods such as desserts, sauces and toppings.

The maximum permitted levels for acesulfame-potassium in Standard 1.3.1 range from 150 mg/kg in electrolyte drink products and 500 mg/kg in liquid milk products and supplementary foods, to 2000 mg/kg in confectionery and 3000 mg/kg in water-based flavoured drinks and fruit juice products. Acesulfame-potassium is also permitted to be used at levels of GMP in tabletop sweeteners.

Acesulfame-potassium is permitted at 450 mg/kg in FSMP in the EU regulations and at GMP in the USA. To be consistent with other maximum levels set in Standard 1.3.1 for acesulfame-potassium, FSANZ considers it would be appropriate to set a maximum level of use, rather than a GMP permission for use in FSMP.

### *Conclusion*

FSANZ concludes that a maximum permitted level in Schedule 1 of Standard 1.3.1 of 450 mg/kg of acesulfame-potassium is appropriate for FSMP, as this level is the same as the maximum permitted level in the EU regulations and similar food products included in Schedule 1 of Standard 1.3.1.

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<sup>2</sup> Maximum level applies to each additive used singly or in combination. If used in combination, there may be no more than 1500 mg/kg total sorbates and benzoates combined (clause 6 of Standard 1.3.1)



### **3.3.2.2 Aspartame**

Aspartame is listed in Standard 1.3.1 as a Schedule 2 food additive. Schedule 2 food additives are permitted in processed foods as a result of use in accordance with GMP unless otherwise prohibited in Schedule 1 of Standard 1.3.1. Clause 4 of Standard 1.3.1 provides additional clarification regarding the requirements for the use of intense sweeteners in foods.

Aspartame is also specifically permitted in some foods in Schedule 1 of Standard 1.3.1, including confectionery (10000 mg/kg), brewed soft drink (1000 mg/kg), electrolyte drinks (150 mg/kg) and formulated beverages (GMP).

FSANZ has already indicated that Schedule 2 food additives are recommended to be permitted in FSMP. Therefore, aspartame will be permitted to be used in FSMP.

#### *Conclusion*

Given that aspartame is a Schedule 2 food additive, and it is proposed that Schedule 2 food additives be permitted in FSMP, FSANZ concludes that aspartame would be permitted to be added to FSMP.

### **3.3.2.3 Saccharin**

Saccharin (and its sodium, potassium and calcium salts) is permitted in a variety of foods including fruit and vegetable spreads, low joule chewing gum, liquid and tablet or powdered tabletop sweeteners, low joule fruit juice products, water-based flavoured drinks, jelly, sauces and toppings.

The maximum permitted levels for saccharin in Standard 1.3.1 range from 50 mg/kg in brewed soft drinks, 80 mg/kg in low joule fruit and vegetable juice products and 150 mg/kg in water based flavoured drinks, up to 1500 mg/kg in fruit and vegetable spreads, low joule chewing gum, sauces and toppings. Saccharin is also permitted to be used at levels of GMP in liquid, tablet and powdered tabletop sweeteners.

Saccharin is permitted at 200 mg/kg in FSMP in the EU regulations. Saccharin is permitted in special dietary foods in the USA at approximately 400 mg/L for beverages (12 mg/fluid ounce), fruit juice drinks and bases or mixes and at 30 mg per serve in processed foods (on this basis, 30 mg in a 100 gram serving would equate to 300 mg/kg of saccharin). However, the permitted levels in the USA are interim levels and are subject to review.

#### *Conclusion*

FSANZ concludes that a maximum permitted level in Schedule 1 of Standard 1.3.1 of 200 mg/kg of saccharin is appropriate for FSMP. This level is the same as the maximum permitted level in the EU regulations. This level is lower than the interim level for beverage type special dietary foods in the USA. However, FSANZ did not receive any objections to this level after consultation with the FSMP industry in 2011.

### **3.3.2.4 Aspartame-acesulphame salt**

Aspartame-acesulphame salt is permitted in a wide variety of foods including liquid milk products, ice creams, fruit and vegetable spreads, confectionery, flour products (including pasta), biscuits, cakes, pastries, tabletop sweeteners, sports foods, meal replacements and supplementary foods, fruit and vegetable juice products, water-based flavoured drinks and mixed foods such as desserts, sauces and toppings.

The maximum permitted levels for acesulfame-potassium in Standard 1.3.1 include 230 mg/kg in electrolyte drink products, 450 mg/kg in flour products and range from 1100 mg/kg to 6800 mg/kg in other food products. Aspartame-acesulphame salt is also permitted to be used at levels of GMP in tabletop sweeteners.

Aspartame-acesulphame salt is permitted at 450 mg/kg in FSMP in the EU regulations but is not permitted in the USA.

#### *Conclusion*

FSANZ concludes that a maximum permitted level in Schedule 1 of Standard 1.3.1 of 450 mg/kg of Aspartame-acesulphame salt is appropriate for FSMP. This level is the same as the maximum permitted level in the EU regulations and was not objected to by the FSMP industry after consultation in 2011.

### **3.3.3 Antioxidants - butylated hydroxyanisole (BHA) and butylated hydroxytoluene (BHT)**

BHA and BHT are permitted, in Schedule 1 of Standard 1.3.1, in a limited number of foods including dried milk powder, edible oils and oil emulsions, walnut and pecan nut kernels, bubble gum and chewing gum. The maximum permitted levels of BHA and BHT permitted in Standard 1.3.1 range from 70 mg/kg in walnut and pecan nut kernels, up to 200 mg/kg in edible oils and oil emulsions (100 mg/kg for BHT). BHA is also permitted in flavourings used in preparations of food additives at 1000 mg/kg. However, use at this level is expected only where flavourings are used in the preparation of food additives and would constitute only a very small proportion of a final food product.

There is no provision for the addition of BHA or BHT to FSMP in the EU regulations.

However, BHA and BHT have GRAS permission in the USA at up to 0.02% of fat or oil content of a food.

BHA and BHT are antioxidants that can act to preserve fats and oils from oxidative damage. The 0.02% GRAS level is based on the fat or oil content of foods, rather than being permitted at 0.02% of the final food product. The 0.02% GRAS level corresponds to 200 mg/kg in the oil or fat content.

FSANZ considers that the existing permissions for BHA and BHT in Schedule 1 of Standard 1.3.1 are appropriate for use in ingredients that may be used to manufacture FSMP. FSANZ does not expect that additional levels of BHA or BHT would be justified outside of the carry-over provisions for ingredients outlined in clause 7 of Standard 1.3.1.

#### *Conclusion*

Given the current maximum use levels for BHA and BHT in Standard 1.3.1, and the permitted level of use in the USA, FSANZ considers that the carry-over provision of clause 7 of Standard 1.3.1 is satisfactory and appropriate for ingredients used in FSMP. FSANZ considers that a separate permission for addition of BHA and BHT in FSMP is not required in Schedule 1 of Standard 1.3.1.

### **3.3.4 Colours**

#### **3.3.4.1 Colours permitted in Schedule 4 of Standard 1.3.1**

At Preliminary Final Assessment, FSANZ proposed to include permission to add Schedule 4 colours to FSMP (in addition to Schedule 2 food additives and Schedule 3 colours). However, the use of colours in foods has come under increasing scrutiny in recent years.

Internationally, food regulators and the food industry have investigated the merits of using alternative sources of colours to add to foods.

Subsequently, in the Consultation Paper released on 15 December 2010, FSANZ amended the recommendation to propose Schedule 4 colours should not be permitted in FSMP. FSANZ noted that at Preliminary Final Assessment, the FSMP industry did not specifically request the addition of Schedule 4 colours to FSMP. However, industry responded that this was because FSANZ did not propose restricting the addition of Schedule 4 colours to FSMP at that time.

Schedule 4 colours are permitted to be added to a variety of processed foods in Standard 1.3.1. In addition, Schedule 4 colours are permitted to be added to FSMP products under EU regulations. Submissions to the Consultation Paper also highlighted the importance of Schedule 4 colours to the formulations of some current FSMP products.

#### *Conclusion*

FSANZ considers that permission to add Schedule 4 colours to FSMP is technologically justified and is consistent with EU regulations.

#### **3.3.4.1 Annatto extracts (requires a permission in Schedule 1 of Standard 1.3.1)**

Annatto extracts are permitted in a variety of foods including a number of dairy products, confectionery, processed cereal products, flour products, biscuits, cakes, pastries, some processed meat products, sports foods, fruit and vegetable juices, formulated beverages and in mixed foods and beverages.

The maximum permitted levels for annatto extracts in commonly consumed foods are 10 mg/kg for beverages and 25 mg/kg for non-beverage products. A limited number of foods are permitted to contain higher levels of annatto extracts. Annatto extracts are permitted to be added to foods in the EU and the USA in accordance with GMP.

#### *Conclusion*

FSANZ concludes that maximum permitted levels in Schedule 1 of Standard 1.3.1 for annatto extracts are appropriate. FSANZ recommends maximum permitted levels of 10 mg/kg for liquid FSMP and 25 mg/kg for non-liquid FSMP. These maximum permitted levels are consistent with those for similar foods in Schedule 1 of Standard 1.3.1.

#### **3.3.4.2 Amaranth (requires a permission in Schedule 1 of Standard 1.3.1)**

Amaranth is permitted in a limited number of foods, including ice cream, fruit spreads, confectionery, roe, sports foods, fruit and vegetable juice products, water-based flavoured drinks, formulated beverages, wine-based drinks, spirits and liqueurs and jelly.

The maximum permitted levels for amaranth in beverage products is 30 mg/kg and in other foods is 290-300 mg/kg. Amaranth is permitted to be added to foods in the EU in accordance with GMP, but is not permitted to be added to foods in the USA.

#### *Conclusion*

FSANZ concludes that maximum permitted levels in Schedule 1 of Standard 1.3.1 for amaranth is appropriate. FSANZ recommends maximum permitted levels of 30 mg/kg for liquid FSMP and 300 mg/kg for non-liquid FSMP. These maximum permitted levels are consistent with those for similar foods in Schedule 1 of Standard 1.3.1.

### **3.3.5 Acidity Regulators**

#### **3.3.5.1 Sodium hydroxide and potassium hydroxide**

Potassium hydroxide and sodium hydroxide are used in some FSMP as acidity regulators. Neither of these are permitted as food additives in Schedule 1 of Standard 1.3.1. However, they are permitted as general processing aids in Standard 1.3.3.

Potassium hydroxide and sodium hydroxide are also generally permitted food additives in a wide variety of foods in the EU at levels in accordance with GMP and are affirmed by the Food and Drug Administration as generally recognised as safe at GMP levels in a wide variety of foods in the USA. Both additives are also permitted (at GMP) in a range of foods, including dietetic foods for special medical purposes, in the Codex GSFA.

#### *Conclusion*

FSANZ concludes that it is appropriate to permit the addition of sodium hydroxide and potassium hydroxide to FSMP in Schedule 1 of Standard 1.3.1. FSANZ recommends they be permitted in accordance with GMP. This is consistent with the permitted use of these additives in the EU and USA.

#### **3.3.5.2 Phosphoric acid**

Phosphoric acid is permitted in cheese and cheese products (at GMP) and in kola type drinks (at 570 mg/kg) in Schedule 1 of Standard 1.3.1. Phosphoric acid is also a generally permitted processing aid in Standard 1.3.3.

Phosphoric acid is permitted to be added as a food additive in a number of foods in the EU, including non-alcoholic flavoured drinks, sterilised and UHT milk, candied fruits, fruit preparations, infant formula and processed cereal based foods and baby foods for infants and young children. Phosphoric acid is also generally recognised as safe by the Food and Drug Administration in the USA when used in accordance with GMP. Phosphoric acid (as part of the phosphates group of additives) is also permitted in a range of foods, including dietetic foods for special medical purposes at levels up to 2200 mg/kg, in the Codex GSFA.

#### *Conclusion*

FSANZ concludes that it is appropriate to permit the addition of phosphoric acid to FSMP in Schedule 1 of Standard 1.3.1. FSANZ recommends phosphoric acid be permitted in accordance with GMP. This is consistent with the permitted use of phosphoric acid in the USA.

### **3.3.6 Other food additives**

FSANZ notes some other Schedule 1 food additives may be present in FSMP imported into Australia and New Zealand. However, the FSMP industry did not request specific permissions for these food additives in FSMP during consultation. The food additives that FSANZ noted are ascorbyl palmitate (INS 304) and tocopherol, d-alpha-, concentrate (INS 307).

Because both of these food additives are antioxidants and their regulation is considered to be similar to the FSANZ position on the antioxidants BHA and BHT (described above), FSANZ considers it likely that the presence of these food additives in FSMP will be suitably addressed by the carry-over provisions in clause 7 of Standard 1.3.1.

### 3.4 Response to Key Assessment Questions

The following questions apply to the food additives requested for addition to FSMP by the FSMP industry:

- a) Has the technological function in FSMP been articulated clearly for these food additives?
- b) Are these food additives safe for use in FSMP?
- c) Is there a need to establish maximum levels for the use of these food additives in FSMP, in order to protect public health and safety? If so, what should they be?

FSANZ concludes that specific permission to add the food additives listed in Table 2 to FSMP is technologically justified at the levels listed in the table, along with permission to add the food additives already listed in Schedules 2, 3 and 4 of Standard 1.3.1.

**Table 2: Recommended food additives in FSMP in Schedule 1 of Standard 1.3.1**

INS Number	Additive Name	Max Permitted Level
123	Amaranth	30 mg/kg (liquid FSMP) 300 mg/kg (non-liquid FSMP)
160b	Annatto extracts	10 mg/kg (liquid FSMP) 25 mg/kg (non-liquid FSMP)
200 201 202 203	Sorbic acid and sodium, potassium and calcium sorbates	1500 mg/kg
210 211 212 213	Benzoic acid and sodium, potassium and calcium benzoates	1500 mg/kg
338	Phosphoric acid	GMP
524	Sodium hydroxide	GMP
525	Potassium hydroxide	GMP
950	Acesulphame potassium	450 mg/kg
954	Saccharin	200 mg/kg
962	Aspartame-acesulphame salt	450 mg/kg

FSANZ concludes it is not necessary to set a maximum permitted level in Schedule 1 of Standard 1.3.1 for aspartame. Aspartame is listed as a Schedule 2 food additive and is therefore permitted in Schedule 1 of Standard 1.3.1 in accordance with GMP. FSANZ also concludes that separate permissions for BHA and BHT in FSMP in Schedule 1 of Standard 1.3.1 are not justified, as the carry-over provisions provided for in clause 7 of Standard 1.3.1 are sufficient for the presence of these food additives in FSMP.

FSANZ concludes that the food additives included in this assessment are safe for use in FSMP at the levels listed in Table 2 and in accordance with the carry-over provisions of Standard 1.3.1. These food additives are concluded to be safe on the basis of a history of consumption of FSMP products containing these additives and previous FSANZ and international risk assessments that have been conducted before their use in other foods (and FSMP internationally).