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ISDI Comments on CCFAC Request for information on additives for inclusion in GSFA

Answer to CL 2006/34-FA

Please note that those ISDI comments include comments that were already sent by ISDI in 2005 in its document 05/317 (also reported in CX/FAC 06/38/9, Part 2) but that were not taken into account by CCFAC.

Additive	INS Number	Food Category No	Food Category	Max Level	Step	Information requested	ISDI Response
Quillaia Extract	999	14.1.4	Water-based flavoured drinks, including "sport" "energy" or "electrolyte" drinks and particulated drinks	200 mg/kg [1]	6	Type 1 or 2? Use level on saponin basis	-
Erythrosine	127	14.1.4	Water-based flavoured drinks, including "sport" "energy" or "electrolyte" drinks and particulated drinks	300 mg/kg	6	Technological need	300 mg/kg supported (see Annex 1) These drinks are designed for use by individuals who are in a specific physiological condition, due to the expenditure of intense muscular effort. A key feature of sport and electrolyte drinks is that they must appeal to the intended consumer. The visual appeal of any beverage is an important aspect of its appeal and organoleptic properties, and the ability to add a range of colours is an important determinant of consumer preference and consumption.

[1] Note 132

Iron Oxides	172 I, 172 ii	13.3	Dietetic foods intended for special medical purposes (excluding products of food category 13.1)	GMP	6	Technological need (including numerical use level)	Not supported by ISDI
Iron Oxides	172 I, 172 ii	13.4	Dietetic formulae for slimming purposes and weight reduction	GMP	6	Technological need (including numerical use level)	Not supported by ISDI
Iron Oxides	172 I, 172 ii	13.5	Dietetic foods (e.g. supplementary foods for dietary use) excluding products of food categories 13.1, 13.4 and 13.6)	GMP	6	Technological need (including numerical use level)	Not supported by ISDI
Carotenes Vegetable	160 aii	13.1.3	Formulae for special medical purposes for infants	30 mg/kg [2]	3	Technological need	Not supported by ISDI
Grape Skin Extract	163 ii	13.1.3	Formulae for special medical purposes for infants	20 mg/kg [3]	3	Technological need	Not supported by ISDI
Polysorbates	432, 433, 434, 435, 436	14.1.4	Water-based flavoured drinks, including "sport" "energy" or "electrolyte" drinks and particulated drinks	10000 mg/kg	3	Technological need	Not supported by ISDI
Aspartame	951	13.3	Dietetic foods intended for special medical purposes (excluding products of food category 13.1)	1000 mg/kg	6	Technological need	1000 mg/kg supported (see Annex 2) Aspartame is currently used in a number of foods for special dietary purposes in the EU and medical foods in the US. These products are used by a limited population under the care of a health professional. Availability of these sweetened palatable products aids patient compliance with an otherwise very restricted diet.

[2] Note 84
[3] Note 84

Acesulfame K	950	13.3	Dietetic foods intended for special medical purposes (excluding products of food category 13.1)	450 mg/kg	6	Technological need	450 mg/kg supported (see Annex 3) Acesulfame Potassium is currently used in a number of foods for special dietary purposes in the EU and medical foods in the US. These products are used by a limited population under the care of a health professional. Availability of these sweetened palatable products aids patient compliance with an otherwise very restricted diet.
Sucralose	955	13.3	Dietetic foods intended for special medical purposes (excluding products of food category 13.1)	400 mg/kg	6	Technological need	400 mg/kg supported (see Annex 4) Acesulfame Potassium is currently used in a number of foods for special dietary purposes in the EU and medical foods in the US. These products are used by a limited population under the care of a health professional. Availability of these sweetened palatable products aids patient compliance with an otherwise very restricted diet.
Saccharin	954	13.3	Dietetic foods intended for special medical purposes (excluding products of food category 13.1)	400 mg/kg	6	Technological need	200 mg/kg supported (see Annex 5) Sodium saccharin is currently used in a number of foods for special medical purposes in the US and medical foods in the US. These products are used by a limited population under the care of a health professional. Availability of these sweetened palatable products aids patient compliance with an otherwise restricted diet.
Neotame	961	13.3	Dietetic foods intended for special medical purposes (excluding products of food category 13.1)	33 mg/kg	6	Technological need	Not supported by ISDI
Cyclamates	952	13.3	Dietetic foods intended for special medical purposes (excluding products of food category 13.1)	400 mg/kg	6	Technological need	Not supported by ISDI

Annex 1: Justifications for use of Erythrosine for Food Category 14.1.4

Justification for use

ISDI would also like to support the ongoing work for Erythrosine (INS 127) for use in Food Category 14.1.4 water-based flavoured drinks, including "sport", "energy" or "electrolyte" drinks and particulate drinks.

ISDI particularly wishes to demonstrate the need for the use of these colours in sport and electrolyte drinks.

These drinks are designed for use by individuals who are in a specific physiological condition, due to the expenditure of intense muscular effort.

A key feature of sport and electrolyte drinks is that they must appeal to the intended consumer.

The visual appeal of any beverage is an important aspect of its appeal and organoleptic properties, and the ability to add a range of colours is an important determinant of consumer preference and consumption.

Safety Issues

ISDI supports the levels proposed for the use of Erythrosine (INS 127) for Food Category 14.1.4.

As noted in the request for comments, this colour has been reviewed by JECFA and ADI set for their safe use.

Additionally, this colour has been approved for use throughout Europe for a range of products, and those listed in Food Category 14.1.4 water-based flavoured drinks, including "sport", "energy" or "electrolyte" drinks and particulate drinks, are not excluded from using colours in Directive 94.36.EC.

Annex 2: Justifications for use of Aspartame for Food Category 13.3

Summary

Intense sweeteners are a vital ingredient in the formulation of Formulae for Special Medical Purposes and Dietetic Foods Intended for Special Medical Purposes (FSMP).

Technological limitations of individual sweeteners and the variety of presentations required for FSMP mean it is vitally important to have a range of permitted sweeteners, including Aspartame, which may be used individually or in combination.

Safety of Aspartame has been assessed by International regulatory authorities, Aspartame is approved for use in a range of foods in the EU (94/35/EC) and in the US (21 CFR172.804).

FSMP are formulated so that intakes of Aspartame remain within the ADI and below the proposed maximum levels. Usage of FSMP is controlled by the recommended intake for a specific age and these products are administered under medical supervision unlike normal foods containing sweeteners.

Patient Acceptability

FSMP are flavoured and sweetened to improve palatability as these products are often taken orally in the dietary management of patients over long periods of time. The availability of a range of flavoured products will aid patient compliance with their dietary regime and therefore lead to better management of their medical condition. Sweet flavours are usually the flavours of choice both from a patient preference point of view and from the point of view of product type. This requires the addition of sweetness by using sucrose or other sweetening agents.

The limitations of sucrose or other bulk sweeteners/sugars as a source of sweetness in FSMP are listed below:

Providing the correct balance of calories to active nutrients is important in FSMP and this can often not be achieved if very high levels of sucrose are required for sweetening purposes.

Where the FSMP is a supplement to the diet, high levels of sucrose in that supplement may provide too many calories on daily basis in addition to normal food intake.

High levels of sucrose increase bulk, resulting in a high volume of feed required to obtain the active nutrients. This can be off-putting to patients and therefore can effect compliance.

The osmolality of FSMP is often high due to high levels of osmotically active components e.g. amino acids, peptides. The addition of sucrose or other sugars as sweetening agents would exacerbate this and may be problematic for patients who cannot tolerate high osmolality formulas, but still require a sweet flavoured palatable product.

For some diseases, carbohydrate free, flavoured formulas may be required, and carbohydrate based ingredients such as sucrose cannot be used at all.

Although there is a need to limit use of sweeteners in foods for young children with good health, restriction of their use in FSMP (used by a very small number of the population) may adversely effect compliance with dietary regimes. The artificial nature of these often very restrictive diets benefits greatly from the addition of flavours and sweeteners. In the interest of ensuring compliance to specialist diets there is a need for the use of a small number of sweeteners in FSMP for young children.

Natural sweetening agents are used whenever possible with sweeteners used only whenever absolutely necessary.

The inclusion of high levels of sugar in FSMP for young children is discouraged to avoid dental caries and particularly for patients on calorie restricted diets

Technological Issues

There are a number of technological issues which are paramount to product design which must be optimised in order to achieve palatable, stable and safe products. FSMP utilise many ingredients which are very different to normal foods. Unpalatable ingredients such as amino acids, peptides and minerals/trace elements are often used at high levels to achieve nutritionally complete formulations. The unpleasant taste of these nutrients is often enhanced in FSMP by the absence of natural taste masking ingredients, such as whole milk proteins and fat. The unpleasant tasting components of many FSMP mean that the maximum permitted level of an appropriate single sweetener may be insufficient to produce a palatable product.

FSMP can be presented in different forms e.g. sterile liquids, powders for reconstitution. Each of these presentations has specific technological requirements for intense sweeteners.

A further limitation is the individual properties or composition of certain sweeteners which can render them unsuitable for particular product applications or disease states.

A combination of permitted sweeteners is therefore often necessary in FSMP. The availability of a range of permitted intense sweeteners allows combination of the different properties of sweeteners and helps to overcome their individual limitations.

The use of sweeteners in FSMP is kept to a minimum and only used for technological reasons. Also unlike other foods containing sweeteners which are consumed by young children, FSMP are consumed under medical supervision and intake is limited to the recommend intake for a specific age group.

Aspartame is the methyl ester of a dipeptide composed of the amino acids L-aspartic acid and L-phenylalanine. Aspartame has sweetness potency approximately 200 times that of sugar. Aspartame also has a clear sweet taste similar to sugar with little after-taste. Aspartame is however unstable in liquid formulation and cannot be used in FSMP which must be phenylalanine free such as low protein or protein supplements used in the dietary management of phenylketonuria.

Safety of Aspartame

Aspartame is used in a wide range of food products in many countries around the world. The EU Scientific Committee on Food (SCF) have evaluated safety of aspartame on a number of occasions (1985, 1989, 1997, 2002)[1]. Aspartame has also been evaluated by the Joint FAO/WHO Expert Committee on Food Additives[2] and the US FDA.[3]

JECFA and the SCF have assigned an ADI of 40mg/kg bw/day to aspartame. Based on published intakes levels in European countries, the SCF concluded that intakes of Aspartame in high level consumers, including adults, children and diabetics range up to 10mg/kg bw/day and are thus unlikely to exceed the ADI (40mg/kg bw/day). The SCF also concluded that data presented in a report suggesting a link between aspartame and an increase in the incidence of brain tumours in the US did not support an increase in the incidence of brain tumours[4]. This data was also evaluated by the FDA[5] and the UK Committee on Carcinogenicity of Chemicals in Food, Consumer Products and the Environment[6,7], both concluded that the data and not support on association between aspartame and an increase in the incidence of brain tumours.

Aspartame has been approved for use in the EU in Complete Formulae and Nutritional Supplements for use under medical supervision (94/35/EC) at a maximum level of 1000 mg/kg and in the US in medical foods (21 CFR 172.804) at GMP level.

Use of Aspartame in FSMP is kept to a minimum and only used for technological reasons. FSMP are formulated so that daily intake of Aspartame remains within the ADI and below the maximum permitted levels. In addition intake of FSMP is controlled by the recommended intake for a specific age group and these products are administered under medical supervision.

Conclusions

Aspartame is currently used in a number of foods for special dietary purposes in the EU and medical foods in the US. These products are used by a limited population under the care of a health professional. Availability of these sweetened palatable products aids patient compliance with an otherwise very restricted diet.

Safety of Aspartame has been reviewed by international regulatory authorities. Products are formulated so that maximum daily intakes of Aspartame are within the ADI assigned by JECFA. The availability of Aspartame to be used singly or in combination with other permitted sweeteners is important in overcoming technological issues present in the formulation of FSMP and for the development of a range of range of products to aid patient compliance.

References

1. Opinion of the Scientific Committee on Food: Update on the Safety of Aspartame SCF/CS/ADD/EDUL/222 Final 10 December 2002
2. Aspartame: Evaluation of Certain Food Additives Joint FAO/WHO Expert Committee on Food Additives. 1980 Technical Report Series 653 WHO Health Organisation Geneva
3. FDA (1984) Food Additives Permitted for Direct Addition to Food for Human Consumption: Aspartame. Food and Drug Administration. Federal Register, 46FR38285
4. Olney JW, Farber NB, Spitznagel E & Robins LN (1996) Increasing Brain Tumor Rates: Is there a Link to Aspartame? J Neuropathol Exp Neurol 55 115-1123
5. FDA (1996). Food and Drug Administration Statement on Aspartame. Talk Paper T96-74 November 18, 1996

COT 1996 Aspartame. Committee on Carcinogenicity of Chemical in Food, Consumer Products and the Environment. Annual Report of the Committees on Toxicity, Mutagenicity and Carcinogenicity. The Stationery Office London pp 56-57

Annex 3: Justifications for use of Acesulfame K for Food Category 13.3

Summary

Intense sweeteners are a vital ingredient in the formulation of Formulae for Special Medical Purposes and Dietetic Foods Intended for Special Medical Purposes (FSMP).

Technological limitations of individual sweeteners and the variety of presentations required for FSMP mean it is vitally important to have a range of permitted sweeteners including Acesulfame Potassium which may be used individually or in combination.

Safety of Acesulfame Potassium has been assessed by International regulatory authorities, Acesulfame Potassium is approved for use in complete formulae and nutritional supplements for use under medical supervision in the EU (94/35/EC) and in medical foods in the US (21 CFR 172.800).

FSMP are formulated so that intakes of Acesulfame Potassium remain within the ADI and below the proposed maximum level (450 mg/kg) which is also consistent with the maximum permitted level in the EU. Usage of FSMP is controlled by the recommended intake for a specific age and is administered under medical supervision unlike normal foods containing sweeteners.

Patient Acceptability

FSMP are flavoured and sweetened to improve palatability as these products are often taken orally in the dietary management of patients over long periods of time. The availability of a range of flavoured products will aid patient compliance with their dietary regime and therefore lead to better management of their medical condition. Sweet flavours are usually the flavours of choice both from a patient preference point of view and from the point of view of product type. This requires the addition of sweetness by using sucrose or other sweetening agents.

The limitations of sucrose or other bulk sweeteners/sugars as a source of sweetness in FSMP are listed below:

Providing the correct balance of calories to active nutrients is important in FSMP and this can often not be achieved if very high levels of sucrose are required for sweetening purposes.

Where the FSMP is a supplement to the diet, high levels of sucrose in that supplement may provide too many calories on daily basis in addition to normal food intake.

High levels of sucrose increase bulk, resulting in a high volume of feed required to obtain the active nutrients. This can be off-putting to patients and therefore can effect compliance.

The osmolality of FSMP is often high due to high levels of osmotically active components e.g. amino acids, peptides. The addition of sucrose or other sugars as sweetening agents would exacerbate this and may be problematic for patients who cannot tolerate high osmolality formulas, but still require a sweet flavoured palatable product.

For some diseases, carbohydrate free, flavoured formulas may be required, and carbohydrate based ingredients such as sucrose cannot be used at all.

Although there is a need to limit use of sweeteners in foods for young children with good health, restriction of their use in FSMP (used by a very small number of the population) may adversely effect compliance with dietary regimes. The artificial nature of these often very restrictive diets benefits greatly from the addition of flavours and sweeteners. In the interest of ensuring compliance to specialist diets there is a need for the use of a small number of sweeteners in FSMP for young children.

Natural sweetening agents are used whenever possible with sweeteners used only whenever absolutely necessary.

The inclusion of high levels of sugar in FSMP for young children is discouraged to avoid dental caries and particularly for patients on calorie restricted diets

Technological Issues

There are a number of technological issues which are paramount to product design which must be optimised in order to achieve palatable, stable and safe products. FSMP utilise many ingredients which are very different to normal foods. Unpalatable ingredients such as amino acids, peptides and minerals/trace elements are often used at high levels to achieve nutritionally complete formulations. The unpleasant taste of these nutrients is often

enhanced in FSMP by the absence of natural taste masking ingredients, such as whole milk proteins and fat. The unpleasant tasting components of many FSMP mean that the maximum permitted level of an appropriate single sweetener may be insufficient to produce a palatable product.

FSMP can be presented in different forms e.g. sterile liquids, powders for reconstitution. Each of these presentations has specific technological requirements for intense sweeteners.

A further limitation is the individual properties or composition of certain sweeteners which can render them unsuitable for particular product applications or disease states.

A combination of permitted sweeteners is therefore often necessary in FSMP. The availability of a range of permitted intense sweeteners allows combination of the different properties of sweeteners and helps to overcome their individual limitations.

Acesulfame Potassium is an intense sweetener with approximately 200 times the sweetness potency of sucrose. Unlike some other sweeteners, Acesulfame Potassium is stable under a wide range of processing conditions tolerating pH levels from 3 to 9 and temperatures up to 2000C. In addition, Acesulfame Potassium has no compositional limitations.

Safety of Acesulfame Potassium

Safety of Acesulfame Potassium has been assessed by both the European Scientific Committee on Foods (SCF)[1] and the Joint FAO/WHO Expert Committee on Food Additives (JECFA)[2,3], JECFA have assigned an ADI of 15 mg/kg bw/day to Acesulfame Potassium, the SCF have assigned an ADI of 0 to 9 mg/kg bw/day. Safety of Acesulfame potassium has also been assessed by the FDA, and an ADI of 15 mg/kg/day assigned.[4]

Based on the evaluation of safety of Acesulfame Potassium, Directive 94/35/EC[5] of the European Parliament permits use of Acesulfame Potassium in complete formulae and nutritional supplements for use under medical supervision at a maximum level of 450 mg/kg. Acesulfame Potassium has now been used in FSMP in the EU for a number of years with no safety concerns.

The US FDA have approved Acesulfame Potassium for use as a general purpose sweetener and flavour enhancer in foods generally apart from meat and poultry at a level consistent with good manufacturing practice (21 CFR 172.800).

Worldwide Acesulfame Potassium is approved in more than 90 countries.

Use of Acesulfame K in FSMP is kept to a minimum and only used for technological reasons. FSMP are formulated so that daily intake of Acesulfame Potassium remains within the ADI and below the maximum permitted level (450 mg/kg as consumed). In addition usage of FSMP is controlled by the recommended intake for a specific age and these products are administered under medical supervision.

Conclusions

Acesulfame Potassium is currently used in a number of foods for special dietary purposes in the EU and medical foods in the US. These products are used by a limited population under the care of a health professional. Availability of these sweetened palatable products aids patient compliance with an otherwise very restricted diet.

Safety of Acesulfame Potassium has been reviewed by international regulatory authorities. Products are formulated so that maximum daily intakes of Acesulfame Potassium are within the ADI assigned by JECFA. The availability of Acesulfame Potassium to be used singly or in combination with other permitted sweeteners is important in overcoming technological issues present in the formulation of FSMP and for the development of a range of products to aid patient compliance.

References

1. SCF Opinion: Re-evaluation of Acesulfame K with reference to the previous SCF opinion of 1991. SCF/CS/ADD/EDUL/194 final 13 March 2000

2. Joint FAO/WHO Expert Committee on Food Additives. Toxicological

   Evaluation of Certain Food Additives. WHO Food Additives Series 18:12-14, 1983. WHO, Geneva.

3. Joint FAO/WHO Expert Committee on Food Additives. Toxicological

   Evaluation of Certain Food Additives. WHO Food Additives Series 28:183-218. 1991 WHO, Geneva.

4. Food Additives Permitted for Direct Addition to Food for Human Consumption; Acesulfame Potassium
Department of Health and Human Services.
Food and Drug Administration 21 CFR Part 172
[Docket No. 2002F-0220] Final rule
http://www.cfsan.fda.gov/~lrd/fr031231.html

5. European Parliament and Council Directive 94/35/EC on Sweeteners for use in Foodstuffs.
Official Journal of the European Community 10.9.94 No L237 pp 3-12

Annex 4: Justifications for use of Sucralose for Food Category 13.3

Summary

Intense sweeteners are a vital ingredient in the formulation of Formulae for Special Medical Purposes and Dietetic Foods Intended for Special Medical Purposes (FSMP).

Technological limitations of individual sweeteners and the variety of presentations required for FSMP mean it is vitally important to have a range of permitted sweeteners, including sucralose, which may be used singly or in combination.

Safety of sucralose has been assessed by international regulatory authorities. Sucralose is approved for use at a maximum level of 400 mg/kg in Foods for Special Medical Purposes in the EU (2003/115/EC) and as a general food sweetener at GMP levels in the US (21CFR 172.831).

FSMP are formulated so that intakes of Sucralose remain within the ADI and below the proposed maximum level (400 mg/kg) which is also consistent with the maximum permitted level in the EU. Usage of FSMP is controlled by the recommended intake for a specific age and is administered under medical supervision unlike normal foods containing sweeteners.

Patient Acceptability

FSMP are flavoured and sweetened to improve palatability as these products are often taken orally in the dietary management of patients over long periods of time. The availability of a range of flavoured products will aid patient compliance with their dietary regime and therefore lead to better management of their medical condition. Sweet flavours are usually the flavours of choice both from a patient preference point of view and from the point of view of product type. This requires the addition of sweetness by using sucrose or other sweetening agents.

The limitations of sucrose or other bulk sweeteners/sugars as a source of sweetness in FSMP are listed below:

Providing the correct balance of calories to active nutrients is important in FSMP and this can often not be achieved if very high levels of sucrose are required for sweetening purposes.

Where the FSMP is a supplement to the diet, high levels of sucrose in that supplement may provide too many calories on daily basis in addition to normal food intake.

High levels of sucrose increase bulk, resulting in a high volume of feed required to obtain the active nutrients. This can be off-putting to patients and therefore can effect compliance.

The osmolality of FSMP is often high due to high levels of osmotically active components e.g. amino acids, peptides. The addition of sucrose or other sugars as sweetening agents would exacerbate this and may be problematic for patients who cannot tolerate high osmolality formulas, but still require a sweet flavoured palatable product.

For some diseases, carbohydrate free, flavoured formulas may be required, and carbohydrate based ingredients such as sucrose cannot be used at all.

Although there is a need to limit use of sweeteners in foods for young children in good health, restriction of their use in FSMP (used by a very small number of the population) may adversely effect compliance with dietary regimes. The artificial nature of these often very restrictive diets benefits greatly from the addition of flavours and sweeteners. In the interest of ensuring compliance to specialist diets there is a need for the use of a small number of sweeteners in FSMP for young children.

Natural sweetening agents are used whenever possible with sweeteners used only when absolutely necessary.

The inclusion of high levels of sugar in FSMP for young children is discouraged to avoid dental caries and particularly for patients on calorie restricted diets

Technological Issues

There are a number of technological issues which are paramount to product design which must be optimised in order to achieve palatable, stable and safe products. FSMP utilise many ingredients which are very different to normal foods. Unpalatable ingredients such as amino acids, peptides and minerals/trace elements are often used at high levels to achieve nutritionally complete formulations. The unpleasant taste of these nutrients is often enhanced in FSMP by the absence of natural taste masking ingredients, such as whole milk proteins and fat. The

unpleasant tasting components of many FSMP mean that the maximum permitted level of an appropriate single sweetener may be insufficient to produce a palatable product.

FSMP can be presented in different forms e.g. sterile liquids, powders for reconstitution. Each of these presentations has specific technological requirements for intense sweeteners.

A further limitation is the individual properties or composition of certain sweeteners which can render them unsuitable for particular product applications or disease states.

A combination of permitted sweeteners is therefore often necessary in FSMP. The availability of a range of permitted intense sweeteners allows combination of the different properties of sweeteners and helps to overcome their individual limitations.

Sucralose has an intensity of between 450 and 600 times the sweetness of sucrose, which is comparable if not higher than other permitted sweeteners. Sucralose has a clean sweet taste, similar to sugar, with little or no after-taste. Sucralose is stable to high temperature processing (such as that required for sterile liquid FSMP) and a wide pH range. Sucralose has a nutritional composition which renders it suitable for all disease applications.

Safety of Sucralose

JECFA reviewed available scientific evidence on sucralose at its 37th Meeting in 1991 and allocated a full ADI of 0 to 15 mg/kg body wt (JECFA, 1991)[1]. Following the allocation of an ADI by JECFA, sucralose has been approved as a sweetener in a number of countries.

The European Scientific Committee on Food (SCF) has also reviewed the safety of sucralose and issued an opinion in 2000 (SCF 2000)[2]. The SCF was satisfied that the range of scientific studies available were sufficient for a full safety evaluation of sucralose. The SCF concluded that sucralose is acceptable as a sweetener for general food use and that an ADI of 0 to 15 mg/kg bw can be established based on application of a 100 fold safety factor to the overall NOEL of 1500 mg/kg bw/day. Based on the SCF opinion, Directive 2003/115/EC amended Directive 94/35/EC on sweeteners for use in foodstuffs to include provisions for use of sucralose (E955) in dietary foods for special medical purposes at a maximum permitted level of 400 mg/kg and as a general food sweetener at GMP levels in the US (21 CFR 172.831).

Use of Sucralose in FSMP is kept to a minimum and only used for technological reasons. FSMP are formulated so that daily intake of Sucralose remains within the ADI and below the maximum permitted level (400 mg/kg as consumed). In addition usage of FSMP is controlled by the recommended intake for a specific age and is administered under medical supervision.

Conclusions

Sucralose is used in foods for special dietary purposes in the EU and medical foods in the US. These products are used by a limited population under the care of a health professional. Availability of these sweetened palatable products aids patient compliance with an otherwise very restricted diet.

Safety of Sucralose has been reviewed by international regulatory authorities. Products are formulated so that maximum daily intakes of Sucralose are within the ADI. The availability of Sucralose to be used singly or in combination with other permitted sweeteners is important in overcoming technological issues present in the formulation of FSMP and for the development of a range of products to aid patient compliance.

References

1) JECFA (1991) Evaluation of certain food additives and contaminants. Thirty-seventh Report of the Joint FAO/WHO Expert Group on Food Additives. WHO Technical Report Series 806. WHO, Geneva.

2) SCF (2000) Opinion of the Scientific Committee on Food on Sucralose

http://europa.eu.int/comm/food/fs/sc/scf/out68_en.pdf

Annex 5: Justifications for use of Saccharine for Food Category 13.3

Summary

Intense sweeteners are a vital ingredient in the formulation of Formula for Special Medical Purposes and Dietetic Foods Intended for Special Medical Purposes (FSMP).

Technological limitations of individual sweeteners and the variety of presentations required for FSMP mean it is vitally important to have a range of permitted sweeteners, including saccharin and its salts, which may be used individually or in combination

Safety of Saccharin and its salts has been assessed by International regulatory authorities. Saccharin is approved for use in complete formula and nutritional supplements for use under medical supervision in the EU (94/35/EC) and in medical foods in the US (21 CFR 180.37).

FSMP are formulated so that intakes of Saccharin and its salts remain within the ADI and below the proposed maximum levels. Usage of FSMP is controlled by the recommended intake for a specific age and is administered under medical supervision unlike normal foods containing sweeteners.

Patient Acceptability

FSMP are flavoured and sweetened to improve palatability as these products are often taken orally in the dietary management of patients over long periods of time. The availability of a range of flavoured products will aid patient compliance with their dietary regime and therefore lead to better management of their medical condition. Sweet flavours are usually the flavours of choice both from a patient preference point of view and from the point of view of product type. This requires the addition of **sweetness** by using sucrose or other sweetening agents.

The limitations of sucrose or other bulk sweeteners/sugars as a source of sweetness in FSMP are listed below:

Providing the correct balance of calories to active nutrients is important in FSMP and this can often not be achieved if very high levels of sucrose are required for sweetening purposes.

Where the FSMP is a supplement to the diet, high levels of sucrose in that supplement may provide too many calories on daily basis in addition to normal food intake.

High levels of sucrose increase bulk, resulting in a high volume of feed required to obtain the active nutrients. This can be off-putting to patients and therefore can effect compliance.

The osmolality of FSMP is often high due to high levels of osmotically active components e.g. amino acids, peptides. The addition of sucrose or other sugars as sweetening agents would exacerbate this and may be problematic for patients who cannot tolerate high osmolality formulas, but still require a sweet flavoured palatable product.

For some diseases, carbohydrate free, flavoured formulas may be required, and carbohydrate based ingredients such as sucrose cannot be used at all.

Although there is a need to limit use of sweeteners in foods for young children with good health, restriction of their use in FSMP (used by a very small number of the population) may adversely effect compliance with dietary regimes. The artificial nature of these often very restrictive diets benefits greatly from the addition of flavours and sweeteners. In the interest of ensuring compliance to specialist diets there is a need for the use of a small number of sweeteners in FSMP for young children.

Natural sweetening agents are used whenever possible with sweeteners used only whenever absolutely necessary.

The inclusion of high levels of sugar in FSMP for young children is discouraged to avoid dental caries and particularly for patients on calorie restricted diets

Technological Issues

There are a number of technological issues which are paramount to product design which must be optimised in order to achieve palatable, stable and safe products. FSMP utilise many ingredients which are very different to normal foods. Unpalatable ingredients such as amino acids, peptides and minerals/trace elements are often used at high levels to achieve nutritionally complete formulations. The unpleasant taste of these nutrients is often enhanced in FSMP by the absence of natural taste masking ingredients, such as whole milk proteins and fat. The

unpleasant tasting components of many FSMP mean that the maximum permitted level of an appropriate single sweetener may be insufficient to produce a palatable product.

FSMP can be presented in different forms e.g. sterile liquids, powders for reconstitution. Each of these presentations has specific technological requirements for intense sweeteners.

A further limitation is the individual properties or composition of certain sweeteners which can render them unsuitable for particular product applications or disease states.

A combination of permitted sweeteners is therefore often necessary in FSMP. The availability of a range of permitted intense sweeteners allows combination of the different properties of sweeteners and helps to overcome their individual limitations. Saccharin is approximately 450 times sweeter than sugar. It is stable at a wide range of pH and temperatures and acts synergistically with other intense sweeteners.

Safety of Saccharin

Saccharin and its sodium, potassium and calcium salts have been evaluated by the EU Scientific Committee on Foods (SCF). The SCF have assigned a full ADI of 5mg/kg BW to sodium saccharin and an ADI of 3.8 mg/kg for the free acid[1]. EU Directive 94/35/EC permits use of saccharin and its sodium, potassium and calcium salts in complete formula and nutritional supplements for use under medical supervision to a maximum level of 200 mg/kg product as consumed. The Joint FAO/WHO Expert Committee on Food Additives (JECFA) have also evaluated safety of saccharin at its 41st meeting and assigned a group ADI of 5 mg/kg bw/d to saccharin and its sodium, potassium and calcium salts[2, 3].

Sodium saccharin has been used in foods for special medical purposes for many years with no specific safety concerns.

Use of Sodium saccharin in FSMP is kept to a minimum and only used for technological reasons. FSMP are formulated so that daily intake of sodium saccharin remains within the ADI and below the maximum permitted levels. In addition usage of FSMP is controlled by the recommended intake for a specific age and these products are administered under medical supervision.

Conclusions

Sodium saccharin is currently used in a number of foods for special medical purposes in the US and medical foods in the US. These products are used by a limited population under the care of a health professional. Availability of these sweetened palatable products aids patient compliance with an otherwise restricted diet.

Products are formulated so that maximum acceptable daily intakes of saccharin and its salts are within the ADI assigned by JECFA. The availability of saccharin and its salts for use singly or in combination with other permitted sweeteners is important in overcoming technological issues present in the formulation of foods for special medical purposes and for developing a range of products which aid patient compliance.

References

1. SCF Opinion on Saccharin and its Sodium, Potassium and Calcium Salts (CS/ADD/EDUL/148-Final February 1997)

2. WHO 1993. Evaluation of Certain Food Additives and Contaminants. WHO Technical Series 837 17-19

WHO 1993. Toxicological Evaluation of Certain Food Additives and Contaminants WHO Additive Series 32 105-133