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PE 386.367v01-00

AMENDMENTS 26-135

Draft report

(PE 384.474v01-00)

Åsa Westlund

Regulation of the European Parliament and of the Council on food additives

Proposal for a regulation (COM(2006)0428 – C6-0260/2006 – 2006/0145(COD))

Text proposed by the Commission

Amendments by Parliament

Amendment by Kathy Sinnott

Amendment 26

Recital 3

(3) This Regulation replaces previous Directives and Decisions concerning food additives permitted for use in foods with a view to ensuring the effective functioning of the internal market and a high level of protection of human health and the interests of consumers via comprehensive and streamlined procedures.

(3) This Regulation replaces previous Directives and Decisions concerning food additives permitted for use in foods with a view to ensuring the effective functioning of the internal market and a high level of protection of human health **and of the environment**, and the interests of consumers, **including those consumers who are intolerant to certain substances**, via comprehensive and streamlined procedures.

Or. en

Justification

Particular consideration should be given to vulnerable groups and allergy sufferers. The majority should be able to eat food sold in normal shops without being referred to special dietary food. One of the criteria for authorisation under this Regulation should therefore be

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that the substance or its use does not reduce the range of foods available to allergy sufferers. The term "intolerant" is more inclusive than "allergic", as it comprises those who have difficulties in digesting certain additives, as well as those who have a specific allergic reaction.

Amendment by Åsa Westlund

Amendment 27

Recital 7

(7) Food additives should be approved and used only if they fulfil the criteria laid down in this Regulation. Food additives must be safe when used, there must be a technological necessity for their use, their must not mislead the consumer and their use must bring a benefit to the consumer.

(7) Food additives should be approved and used only if they fulfil the criteria laid down in this Regulation. Food additives must be safe when used, there must be a technological necessity for their use, their must not mislead the consumer and their use must bring a benefit to the consumer.

Misleading the consumer includes, but is not limited to, issues related to the quality of the ingredients used, the naturalness of a product or of the production process, its nutritional quality and its fruit and vegetable content.

Or. en

Justification

This is required so there is an improved common understanding of the meaning of the phrase "misleading the consumer".

Amendment by Anja Weisgerber

Amendment 28

Recital 7, subparagraph 1 a (new)

Misleading the consumer includes, but is not limited to, issues related to freshness, the quality of the ingredients used, the naturalness of a product or of the production process or the nutritional quality of the product.

Or. de

Justification

This list, which is not exhaustive, is intended to clarify the concept of misleading.

Amendment by Mojca Drčar Murko

Amendment 29

Recital 8

(8) Food additives must ***at all times*** comply with the approved specifications. The specification should include information to adequately identify the food additive, including origin and to describe the acceptable criteria of purity. The specifications previously developed for food additives included in Commission Directive 95/31/EC of 5 July 1995 laying down specific criteria of purity concerning sweeteners for use in foodstuffs , Commission Directive 95/45/EC of 26 July 1995 laying specific purity criteria concerning colours for use in foodstuffs and Commission Directive 96/77/EC of 2 December 1996 laying down specific purity criteria on food additives other than colours and sweeteners should be maintained until the corresponding additives are entered in the Annexes to this Regulation. At that time, the specifications related to such additives should be set out in a Regulation. Those specifications should relate directly to the additives included in the Community lists in the Annexes to this Regulation. However, considering the complex character and substance of such specifications for the sake of clarity, they should not be integrated as such in *the* those Community lists but should be set out in one or more separate Regulations.

(8) Food additives must comply with the approved specifications. The specification should include information to adequately identify the food additive, including origin, and to describe the acceptable criteria of purity. The specifications previously developed for food additives included in Commission Directive 95/31/EC of 5 July 1995 laying down specific criteria of purity concerning sweeteners for use in foodstuffs , Commission Directive 95/45/EC of 26 July 1995 laying specific purity criteria concerning colours for use in foodstuffs and Commission Directive 96/77/EC of 2 December 1996 laying down specific purity criteria on food additives other than colours and sweeteners should be maintained until the corresponding additives are entered in the Annexes to this Regulation. At that time, the specifications related to such additives should be set out in a Regulation. Those specifications should relate directly to the additives included in the Community lists in the Annexes to this Regulation. However, considering the complex character and substance of such specifications, for the sake of clarity they should not be integrated as such in those Community lists but should be set out in one or more separate Regulations.

Or. en

Justification

The words at all times should be deleted since food additives, after dissolving or being mixed with other additives or ingredients, can no longer conform to the established specifications in

all aspects such as with regard to water content.

Amendment by Avril Doyle

Amendment 30

Recital 8

(8) Food additives must ***at all times*** comply with the approved specifications. The specification should include information to adequately identify the food additive, including origin and to describe the acceptable criteria of purity. The specifications previously developed for food additives included in Commission Directive 95/31/EC of 5 July 1995 laying down specific criteria of purity concerning sweeteners for use in foodstuffs , Commission Directive 95/45/EC of 26 July 1995 laying specific purity criteria concerning colours for use in foodstuffs and Commission Directive 96/77/EC of 2 December 1996 laying down specific purity criteria on food additives other than colours and sweeteners should be maintained until the corresponding additives are entered in the Annexes to this Regulation. At that time, the specifications related to such additives should be set out in a Regulation. Those specifications should relate directly to the additives included in the Community lists in the Annexes to this Regulation. However, considering the complex character and substance of such specifications for the sake of clarity, they should not be integrated as such in *the* those Community lists but should be set out in one or more separate Regulations.

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Or. en

Justification

The words "at all times" should be deleted, since food additives, after dissolving or being mixed with other additives or ingredients, can of course no longer conform to the established

specifications in all aspects (for example, with regard to water content).

Amendment by Pilar Ayuso

Amendment 31

Recital 12

(12) A food additive which falls within the scope of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed should be authorised under that Regulation **prior to its approval** under this Regulation.

(12) A food additive which falls within the scope of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed should be authorised under that Regulation **as well as** under this Regulation.

Or. en

Justification

It was understood that, under Regulation (EC) No 1829/2003, a ‘one-door-one-key’ procedure for the authorisation of GM derived foods and food ingredients would be adopted. The requirement for a GM derived food additive to be authorised in accordance with 1829/2003 before it may be assessed for inclusion in Annexes II and III of the proposed food additives Regulation appears to go against this approach and may result in the additive having to undergo two separate authorisation procedures. This would be excessively bureaucratic and could lead to delays.

A stream-lined procedure for authorising GM derived food additives should be ensured, in-line with the ‘one-door-one-key’ approach intended under Regulation (EC) No 1829/2003, that is, that when evaluation for authorisation under 1829/2003/EC and under this Regulation are required, they are both carried out jointly under one single EFSA assessment, instead of following two separate authorisation procedures.

Amendment by Avril Doyle

Amendment 32

Recital 12

(12) A food additive which falls within the scope of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed should be authorised under that Regulation **prior to its approval** under this Regulation.

(12) A food additive which falls within the scope of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed should be authorised under that Regulation, **as well as** under this Regulation.

Or. en

Justification

It was understood that, under Regulation (EC) No 1829/2003, a 'one-door-one-key' procedure for the authorisation of GM derived foods and food ingredients would be adopted. The requirement for a GM derived food additive to be authorised in accordance with 1829/2003 before it may be assessed for inclusion in Annexes II and III of the proposed food additives Regulation appears to go against this approach and may result in the additive having to undergo two separate authorisation procedures. This would be excessively bureaucratic and could lead to delays.

Amendment by Horst Schnellhardt

Amendment 33 Article 1, point b

(b) conditions of use of food additives in foods, **in** food additives and **in** food enzymes;

(b) conditions of use of food additives in foods, **including** food additives and food enzymes **as referred to in European Parliament and Council Regulation (EC) XY/2006 on food enzymes and including food flavourings as referred to in European Parliament and Council Regulation (EC) XY/2006 on food flavourings and certain food additives with flavouring properties;**

Or. de

Justification

This regulation should refer to the whole food additive package, as this will avoid the need for subsequent corrections.

Amendment by Avril Doyle

Amendment 34 Article 1, point (b)

(b) conditions of use of food additives in foods, in food additives **and** in food enzymes;

(b) conditions of use of food additives in foods, in food additives, in food enzymes **and in food flavourings;**

Or. en

Justification

The Commission and Member States have apparently agreed the explicit inclusion of additives used in 'food flavourings' in Annex III, for consistency in the application of rules for 'additives to additives'. [Flavourings are now covered under 'foods' as specified in the Definitions – Article 3: "(ii) foods, whether dried or in concentrated form, including flavourings...]". There should be a consistent approach in the rules applying to additives used in additives, enzymes and flavourings and a consistent revision of the provisions in this respect in the whole text should be ensured if such rules are modified from the current provisions.

Amendment by Åsa Westlund

Amendment 35
Article 1 a (new)

Article 1a

Foodstuffs which contain additives that do not comply with this Regulation shall not be placed on the market.

Or. en

Justification

This makes explicit what is already implicit in the proposal but which is not stated clearly within the current text. If foodstuffs contain additives which do not comply with the requirements of this regulation, then they shall not be permitted on the market.

Amendment by Kathy Sinnott

Amendment 36
Article 2, paragraph 2, point (b)

(b) substances used for the protection of plants and plant products in conformity with Community rules relating to plant health;

(b) substances used for the protection of plants and plant products in conformity with Community rules relating to plant health, ***unless they remain in the final product;***

Or. en

Amendment by Carl Schlyter, Bart Staes

Amendment 37

Article 2, paragraph 2, point (b)

(b) substances used for the protection of plants and plant products in conformity with Community rules relating to plant health;

(b) substances used for the protection of plants and plant products in conformity with Community rules relating to plant health, ***with the exception of post-harvest plant protection products used as conserving agents;***

Or. en

Justification

Post-harvest pesticides like Methylcyclopropene (1-MCP) used for conserving fruit and vegetables (mainly apples) shall fall within the scope of this regulation.

Amendment by Ria Oomen-Ruijten

Amendment 38

Article 2, paragraph 2, point (d a) (new)

(da) microbial cultures that are used in the production of food and which may produce food additives but which are not specifically used to produce them.

Or. en

Justification

1. To create consistency with the Proposal for a Regulation on Food Enzymes (COM (2006) 425 final , Article 2.4) and to harmonize regulations in the Authorisation package (COM (2006) 423 final), microbial cultures producing food additives should be excluded from the scope of the draft regulation.

2. Microbial cultures that are used to produce fermented products (e.g. yoghurt, cheese, sausages, sauerkraut) are not to be considered as enzymes or additives, although they are- by nature- able to produce them. The presence of these additives that are actually generated by the fermentation process during the manufacture of the food, primarily do not have a technological function in itself. This would avoid case by case discussion and legal uncertainty.

Amendment by Åsa Westlund

Amendment 39
Article 2, paragraph 5

5. Where necessary, it may be decided in accordance with the procedure referred to in Article **28(2)** as to whether or not a given substance falls within the scope of this Regulation.

5. Where necessary, it may be decided in accordance with the **regulatory** procedure **with scrutiny** referred to in Article **28(2a)** whether or not a given substance falls within the scope of this Regulation.

Or. en

Justification

This amendment is needed in order to align the text to the provisions of the new comitology decision.

Amendment by Ria Oomen-Ruijten

Amendment 40
Article 3, paragraph 2, point (a), introduction

(a) ‘food additive’ shall mean any substance not normally consumed as a food in itself and not normally used as a characteristic ingredient of food, whether or not it has nutritive value, the intentional addition of which to food for a technological purpose in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food results, or may be reasonably expected to result, in it or its by-products becoming directly or indirectly a component of such foods; **however**, the following are not considered to be food additives:

(a) ‘food additive’ shall mean any substance not normally consumed as a food in itself and not normally used as a characteristic ingredient of food, whether or not it has nutritive value, the intentional addition of which to food for a technological purpose in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food results, or may be reasonably expected to result, in it or its by-products becoming directly or indirectly a component of such foods; the following are not considered to be food additives:

Or. en

Justification

The substances identified in the list that follows in paragraph 2((a)) are food ingredients other than - and different from food additives. The word "however" can be deleted in order to avoid confusion that one of these substances could have been considered a food additive.

Amendment by Ria Oomen-Ruijten

Amendment 41

Article 3, paragraph 2, point (a) (i)

(i) **foods containing** monosaccharides, disaccharides or oligosaccharides used for their sweetening properties;

(i) monosaccharides, disaccharides or oligosaccharides **and foods containing them** used for their sweetening properties;

Or. en

Justification

Since mono- and disaccharides (and to a limited extent short chain oligosaccharides), have sweetening properties, exclusion should therefore directly refer to the substances themselves, rather than to the foods that contain these substances. It would therefore logically follow that foods containing these substances could not be considered as food additives.

Amendment by Horst Schnellhardt

Amendment 42

Article 3, paragraph 2, letter (a) (i)

(i) foods **containing** monosaccharides, disaccharides or oligosaccharides used for their sweetening properties;

(i) foods **which contain** monosaccharides, disaccharides or oligosaccharides **and are** used for their sweetening properties;

Or. de

Justification

The purpose of the amendment is to delete the word 'Süßungsmittel' (sweetener) which is used in the German version of the proposal to describe monosaccharides, disaccharides and oligosaccharides. This term should be reserved for additives.

Amendment by Anja Weisgerber

Amendment 43

Article 3, paragraph 2, point (a) (i)

(i) foods **containing** monosaccharides, disaccharides or oligosaccharides used for their sweetening properties;

(i) foods **which contain** monosaccharides, disaccharides or oligosaccharides **and are** used for their sweetening properties;

Or. de

Justification

The purpose of the amendment is to delete the word 'Süßungsmittel' (sweetener) which is used in the German version of the proposal to describe monosaccharides, disaccharides and oligosaccharides. This term should be reserved for additives.

Amendment by Horst Schnellhardt

Amendment 44

Article 3, paragraph 2, point (a) (ii)

(ii) foods, whether dried or in concentrated form, including flavourings incorporated during the manufacturing of compound foods, because of their aromatic, sapid or nutritive properties together with a secondary colouring effect;

(ii) foods, whether dried or in concentrated form, including flavourings incorporated during the manufacturing of compound foods, because of their aromatic, sapid or nutritive properties together with a secondary colouring effect **and an additional technological effect**;

Or. de

Justification

In this connection, not only colouring effects are of interest: so is any technological effect, such as an antioxidative effect. Moreover, technological effects, for example in the case of food colourings, are not just side-effects (bearing in mind that the German version of the proposal uses the word 'Nebenwirkung' (side-effect) where the English version has 'secondary effect').

Amendment by Ria Oomen-Ruijten

Amendment 45

Article 3, paragraph 2, point (a) (ii)

(ii) foods, whether dried or in concentrated form, including flavourings incorporated during the manufacturing of compound foods, because of their aromatic, sapid or nutritive properties together with a secondary **colouring** effect;

(ii) foods, whether dried or in concentrated form, including flavourings incorporated during the manufacturing of compound foods, because of their aromatic, sapid or nutritive properties together with a secondary effect, **e.g. colouring**;

Or. en

Justification

Paragraph refers to foodstuffs often used not for their aromatic, sapid or nutritive properties, but because of another secondary effect, such as colouring properties ; therefore we suggest to cite the colouring effect as an example.

Amendment by Avril Doyle

Amendment 46

Article 3, paragraph 2, point (a) (viii)

(viii) blood plasma, edible gelatin, protein hydrolysates and their salts, milk protein and gluten;

(viii) blood plasma, **blood proteins**, edible gelatin, protein hydrolysates and their salts, milk protein and gluten;

Or. en

Justification

“Blood proteins” should be added to this list. Blood plasma was the first blood fraction or blood protein to be used in foodstuffs. Meanwhile other blood fractions / blood proteins have been developed with similar applications as the proteins mentioned in the list of Art. 3.2. ((a) (viii)).

Amendment by Ria Oomen-Ruijten

Amendment 47

Article 3, paragraph 2, point (e) (i) and (ii)

(i) any added monosaccharides, disaccharides **or oligosaccharides**; or

(i) any added monosaccharides **or** disaccharides; or

(ii) food containing monosaccharides, disaccharides **or oligosaccharides** which is used for its sweetening properties;

(ii) food containing monosaccharides **or** disaccharides which is used for its sweetening properties;

Or. en

Justification

To create consistency with Directive 94/35 on sweeteners for use on foodstuffs, Directive 90/496 on nutritional labelling and Regulation 1924/2006 on Nutrition and Health Claims, the definition of food with no added sugar should only refer to mono- or diccharides. References to oligosaccharides should therefore be removed.

Amendment by Horst Schnellhardt

Amendment 48

Article 3, paragraph 2, point (f)

(f) ‘energy-reduced food’ shall mean a food with an energy value reduced by at least **30%** compared with the original food or a similar product;

(f) ‘energy-reduced food’ shall mean a food with an energy value reduced by at least **25%** compared with the original food or a similar product;

Or. de

Justification

The Codex Alimentarius calls for a 25 % reduction in energy content. As the discrepancy which has existed so far has repeatedly led to trade barriers, the amendment is necessary.

Amendment by Bogusław Sonik

Amendment 49

Article 3, paragraph 2, point (f)

(f) ‘energy-reduced food’ shall mean a food with an energy value reduced by at least **30%** compared with the original food or a similar product;

(f) ‘energy-reduced food’ shall mean a food with an energy value reduced by at least **25%** compared with the original food or a similar product;

Or. pl

Justification

The requirement to reduce the energy value of a food by at least 30% in order for it to be classified as ‘energy reduced’ is difficult to achieve and out of line with international norms, i.e. Codex Alimentarius. If the 30% threshold is maintained, innovation in the area of energy reduced foods will be impeded, which is regrettable in light of the current concerns about obesity. This does not fit well with overall policy to reformulate foods to offer ‘healthier’ options which should include energy reduced foods. The threshold should be revised to 25% in line with the internationally agreed Codex Alimentarius guidelines.

Amendment by Avril Doyle

Amendment 50

Article 3, paragraph 2, point (f)

(f) ‘energy-reduced food’ shall mean a food

(f) ‘energy-reduced food’ shall mean a food

with an energy value reduced by at least **30%** compared with the original food or a similar product;

with an energy value reduced by at least **25%** compared with the original food or a similar product;

Or. en

Justification

The requirement to reduce the energy value of a food by at least 30% in order for it to be classified as 'energy reduced' is difficult to achieve and out of line with international norms, i.e. Codex Alimentarius. If the 30% threshold is maintained, innovation in the area of energy reduced foods will be impeded, which is regrettable in light of the current concerns about obesity. This does not fit well with overall policy to reformulate foods to offer 'healthier' options which should include energy reduced foods. The threshold should be revised to 25% in line with the internationally agreed Codex Alimentarius guidelines.

Amendment by John Bowis

Amendment 51

Article 3, paragraph 2, point (f)

(f) 'energy-reduced food' shall mean a food with an energy value reduced by at least **30%** compared with the original food or a similar product;

(f) 'energy-reduced food' shall mean a food with an energy value reduced by at least **25%** compared with the original food or a similar product;

Or. en

Justification

This change paves the way for harmonisation with international standards. Under the Codex standard a claim of "energy reduced" can be made where there is an energy reduction of 25%. Whilst the limit in this proposal is about the condition which must be met in order to use sweeteners, change here would pave the way for alignment of the EU and Codex standards on nutrition claims.

Amendment by Avril Doyle

Amendment 52

Article 3, paragraph 2, point (g)

(g) 'table-top sweeteners' shall mean preparations of permitted sweeteners, which may contain other food additives and/or food ingredients and which are intended for sale

(g) 'table-top sweeteners' shall mean preparations of permitted sweeteners, which may contain other food additives and/or food ingredients and which are intended for sale

to the final consumer as a substitute for **sugar**.

to the final consumer as a substitute for **sugars**.

Or. en

Justification

The definition should refer to “sugars” instead of “sugar” insofar as sugar (i.e. sucrose) is not the only nutritive carbohydrate with sweetening properties.

Amendment by Ria Oomen-Ruijten

Amendment 53

Article 3, paragraph 2, point (g a) (new)

(ga) 'food reduced in sugars' shall mean a food in which the total reduction in content of monosaccharides and disaccharides is at least 30% compared to a similar product.

Or. en

Justification

- 1. To create consistency with the Regulation 1924/2006 on Nutrition and Health Claims; The possibility for use of the "reduced" claims in Regulation 1924/2006 is when the content of a specific nutrient (typically fat or sugars) is reduced by at least 30% compared to a similar product.*
- 2. To create legal clarity, a definition of reduced-sugar food should be incorporated into this legislation.*
- 3. The reference to monosaccharides and disaccharides in this definition is in line with Article 2 (e) (i) and (ii) and should also be used here to avoid any misinterpretation of the word "sugars".*

Amendment by Avril Doyle

Amendment 54

Article 3, paragraph 2, point (g b) (new)

(gb) 'Quantum satis' shall mean that no maximum level is specified. However, additives shall be used in accordance with good manufacturing practice, at a level not higher than is necessary to achieve the intended purpose and provided the consumer is not misled¹.

¹ Definition adapted from Article 2(5) of Directive 94/35/EC (sweeteners)

Or. en

Justification

Quantum satis: A definition for 'quantum satis', referred to in Article 10.2, should be included in this article with the other definitions.

Amendment by Horst Schnellhardt

Amendment 55
Article 4, paragraph 1

1. Only food additives included in the Community list in Annex II may be placed on the market as such and used in foods, ***including foodstuffs for particular nutritional uses falling within the scope of Directive 89/398/EEC.***

1. Only food additives included in the Community list in Annex II may be placed on the market as such and used in foods ***for the purposes referred to and included there.***

Or. de

Justification

The connection between additives and the purposes for which they are used which is made in Directive 95/2/EC should be included in the new regulation as well in order to prevent abuse and legal uncertainty.

Amendment by Avril Doyle

Amendment 56
Article 4, paragraph 5

5. Food additives shall ***at all times*** comply with the specifications as referred to in Article 12.

5. Food additives shall comply with the specifications as referred to in Article 12.

Or. en

Justification

The words "at all times" should be deleted, since food additives, after dissolving or being mixed with other additives or ingredients, can of course no longer conform to the established

specifications in all aspects (for example, with regard to water content).

Amendment by Mojca Drčar Murko

Amendment 57
Article 4, paragraph 5

5. Food additives shall ***at all times*** comply with the specifications as referred to in Article 12.

5. Food additives shall comply with the specifications as referred to in Article 12.

Or. en

Justification

The words at all times should be deleted since food additives, after dissolving or being mixed with other additives or ingredients, can no longer conform to the established specifications in all aspects such as with regard to water content.

Amendment by Horst Schnellhardt

Amendment 58
Article 4 a (new)

Article 4a

No food additive and/or food containing such a food additive may be placed on the market and/or in circulation if the use of this food enzyme does not comply with the requirements of this Regulation.

Or. de

Justification

The explicit ban on the use of such substances is in the interests of the clearer administration of justice and is intended to avoid legal uncertainties in advance.

Amendment by Kathy Sinnott

Amendment 59
Article 5, paragraph 1, point (a)

(a) it does not, on the basis of the scientific evidence available, pose a safety concern to the health of the consumer at the level of use proposed;

(a) it does not, on the basis of the scientific evidence available, pose a safety concern to the health of the consumer at the level ***or under the conditions*** of use proposed;

Or. en

Justification

The health of the consumer may be adversely affected by the conditions of the use of the additive. Changes in temperature, for example, may render a substance more toxic. One example of this is Aspartame: studies have shown that when it is heated, it breaks down into several substances, some of which (such as methanol) are toxic.

Amendment by Åsa Westlund

Amendment 60

Article 5, paragraph 1, point (b)

(b) there is a reasonable and technological need that cannot be achieved by other economically and technological practicable means;

(b) there is a reasonable and technological need, ***in terms of benefits to the consumer***, that cannot be achieved by other economically and technological practicable means;

Or. en

Justification

If there are alternatives which entail less of a risk to human health and freedom of choice, and to the environment, these should be used in the first instance.

Amendment by Kathy Sinnott

Amendment 61

Article 5, paragraph 1, point (c a) (new)

(ca) it will not contribute to reducing the range of food available to allergy sufferers or to those intolerant to certain foods.

Or. en

Justification

An additive or a use of an additive may have both advantages and disadvantages according to the above criteria. Ultimately, therefore, the various pros and cons must be weighed against each other. The term "intolerant" is more inclusive than "allergic", as it comprises those who have difficulties in digesting certain additives, as well as those who have a specific allergic reaction.

Amendment by Carl Schlyter, Bart Staes

Amendment 62

Article 5, paragraph 1 a (new)

1a. Nanoparticles may not be used as food additives.

Or. en

Justification

Nanoparticles need a specific risk assessment. The provisions of this regulation are not suited to evaluate specific risks linked to this evolving technology. If nanoparticles are to be used in food production, specific legislation should cover such uses.

Amendment by Kathy Sinnott

Amendment 63

Article 5, paragraph 1 b (new)

1b. Even if an additive may affect health in accordance with paragraph 1(aa), the environment in accordance with paragraph 1(cb) or the range of products available to allergy sufferers or to those intolerant to certain foods in accordance with paragraph 1(ca), it may be authorised if the advantages to consumers as specified in paragraph 2 outweigh those disadvantages.

Or. en

Justification

An additive or a use of an additive may have both advantages and disadvantages according to the above criteria. Ultimately, therefore, the various pros and cons must be weighed against

each other. The term "intolerant" is more inclusive than "allergic", as it comprises those who have difficulties in digesting certain additives, as well as those who have a specific allergic reaction.

Amendment by Åsa Westlund

Amendment 64

Article 5, paragraph 2, point (c)

(c) enhancing the keeping quality or stability of a food or improving its organoleptic properties, provided that the nature, substance or quality of the food is not changed in such a way as to mislead the consumer;

(c) enhancing the keeping quality or stability of a food or improving its organoleptic properties, provided that the nature, substance or quality of the food is not changed in such a way as to mislead the consumer. ***This would include for example freshness, quality of the ingredients used, naturalness of a product and fruit and vegetable content;***

Or. en

Amendment by David Martin, Åsa Westlund

Amendment 65

Article 5, paragraph 3 a (new)

3a. With the exception of proprietary knowledge and information which it is appropriate to keep confidential, the approval of a food additive will refer explicitly and transparently to the considerations given to the criteria laid down in paragraphs 1 to 3, and will explain the basis for the final decision.

Or. en

Justification

This increases the openness and transparency of the authorisation of additives by publicly stating how the authorisation meets the conditions laid down in the proposal.

Amendment by John Bowis

Amendment 66
Article 5, paragraph 3 a (new)

3a. With the exception of proprietary knowledge and information which it is appropriate to keep confidential, the approval of a food additive will refer explicitly and transparently to the considerations given to the criteria laid down in paragraphs 1 to 3, and will explain the basis for the final decision.

Or. en

Justification

his increases the openness and transparency of the authorisation of additives by publicly stating how the authorisation meets the conditions laid down in the proposal.

Amendment by Ria Oomen-Ruijten

Amendment 67
Article 6, point (a)

(a) replacing sugars for the production of energy-reduced food, non-carcinogenic food or food with no added sugars;

(a) replacing sugars for the production of energy-reduced food, non-carcinogenic food, ***food reduced in sugars*** or food with no added sugars;

Or. en

Justification

- 1. To create consistency with the Regulation 1924/2006 on Nutrition and Health Claims, that allows for a "reduced sugar" claim.*
- 2. To create legal clarity, a definition of reduced-sugar food should be incorporated into this legislation.*

Amendment by Carl Schlyter, Bart Staes

Amendment 68
Article 6, point (b)

(b) extending shelf life through the replacement of sugars;

deleted

Or. en

Justification

Extension of shelf life is not the main purpose for using sweeteners, and is not covered by the definition of sweeteners provided in Annex I. If sweeteners shall be used for extending shelf life, they should be authorised according to the provisions of Article 5.

Amendment by Anja Weisgerber

Amendment 69
Article 6, point (b)

(b) extending shelf life *through the replacement of sugars*;

(b) extending shelf life;

Or. de

Justification

Replacing sugars with substitute ingredients will not always extend the shelf life.

Amendment by Avril Doyle

Amendment 70
Article 6, point (b)

(b) extending shelf life *through the replacement of sugars*;

(b) extending shelf life;

Or. en

Justification

The replacement of sugars with sweeteners does not in itself extend the shelf life.

Amendment by Carl Schlyter, Bart Staes

Amendment 71
Article 7

A food additive may be included in the Community list in Annex II for the functional class of colour only if, in addition to serving one or more of the purposes set out in Article 5(2), it also serves **one of the following purposes**:

- (a) restoring the original appearance of food of which the colour has been affected by processing, storage, packaging and distribution, whereby visual acceptability may have been impaired;***
- (b) making food more visually appealing;***
- (c) giving colour to food otherwise colourless.***

A food additive may be included in the Community list in Annex II for the functional class of colour only if, in addition to serving one or more of the purposes set out in Article 5(2), it also serves the ***purpose of restoring the original appearance of food of which the colour has been affected by processing, storage, packaging and distribution, whereby visual acceptability may have been impaired, without however misleading consumers into thinking that the food is fresher or less intensively processed than it is.***

Or. en

Justification

The use of colours shall not mislead the consumers by making “unattractive” food visually attractive, by giving the wrong impression that certain ingredients have been used or by making consumers believe that a highly processed food is more natural or fresh than it actually is.

Amendment by Mojca Drčar Murko

Amendment 72
Article 7, points (b) and (c)

- (b) making food more visually appealing;**
- (c) giving colour to food otherwise colourless.***

(b) making food more visually appealing, e.g. helping to identify flavours normally associated with particular foods or giving colour to foods otherwise colourless.

Or. en

Justification

The existing Directive on colours permits the use of colours to help identify flavours normally associated with particular foods and to give colour to foods otherwise colourless. This provision should be retained in the proposed Regulation.

Amendment by Ria Oomen-Ruijten

Amendment 73

Article 7, points (b) and (c)

(b) making food more visually appealing;

(b) making food more visually appealing,
e.g. helping to identify flavours normally associated with particular foods or giving colour to foods otherwise colourless.

(c) giving colour to food otherwise colourless.

Or. en

Justification

The existing directive on colours also permits the use of colour to help identify flavours normally associated with particular foods and to give colour to foods otherwise colourless. This provision should be retained in the proposed Regulation.

Amendment by Avril Doyle

Amendment 74

Article 7, points (b) and (c)

(b) making food more visually appealing;

(b) making food more visually appealing,
e.g. helping to identify flavours normally associated with particular foods or giving colour to foods otherwise colourless.

(c) giving colour to food otherwise colourless.

Or. en

Justification

The existing directive on colours also permits the use of colours to help identify flavours normally associated with particular foods and to give colour to foods otherwise colourless. It

is very important that this provision is retained in the proposed Regulation.

Amendment by Carl Schlyter, Bart Staes

Amendment 75
Article 7 a (new)

Article 7 a

Specific conditions for flavour enhancers

A food additive may be authorised as a flavour enhancer only if:

(a) the technological need is clearly demonstrated and the desired effect cannot be achieved by using spices;

(b) it does not mislead the consumer into thinking that spices have been used to achieve the taste of the food.

Or. en

Justification

The use of flavour enhancers shall not mislead the consumers. It shall not be authorised for reducing the amount of (more expensive) spices in a processed food.

Amendment by Horst Schnellhardt

Amendment 76
Article 8, paragraph 1

1. Food additives may be assigned to one of the functional classes in Annex I on the basis of the principal ***technological*** function of the food additive.

Allocating a food additive to a functional class shall not preclude it from being used for several functions.

1. Food additives may be assigned to one of the functional classes in Annex I on the basis of the principal function of the food additive ***and may only be used on account of this function.***

Or. de

Justification

The connection between additives and the purposes for which they are used which is made in Directive 95/2/EC should be included in the new regulation as well in order to prevent abuse and legal uncertainty. Moreover, the term 'technological' is merely misleading here.

Amendment by Åsa Westlund

Amendment 77
Article 8, paragraph 2

2. Where necessary, as a result of scientific progress or technological development, additional functional classes may be added to Annex I ***in accordance with the procedure referred to in Article 28(2)***.

2. Where necessary, as a result of scientific progress or technological development, additional functional classes may be added to Annex I.

Or. en

Justification

This amendment is needed in order to keep under codecision any modification to the Annexes of this Regulation.

Amendment by Avril Doyle

Amendment 78
Article 9, paragraph 2, points (a) and (b)

(a) the name of the food additive and ***its*** E number if one has been assigned;

(a) the name of the food additive, ***additive group*** and E number if one has been assigned;

(b) the foods to which the food additive may be added;

(b) the foods ***and/or food additives and/or food enzymes and/or food flavourings*** to which the food additive may be added;

Or. en

Justification

Article 9.2 (a) : The Community list should be complete in the information relating to the additives in the list with the name of the additive, additive group, and E number.

Article 9.2 (b): Correction for consistency, because article 9.2 refers to additives in Annex II (additives in foods) as well as Annex III (additives /enzymes/ flavourings).

Amendment by Kathy Sinnott

Amendment 79

Article 9, paragraph 2, point (d a) (new)

(da) the other food additives which may not be used in combination with the food additive;

Or. en

Justification

Some additives interact to create a new compound, which has different properties and implications for human health or the environment than the two component substances. If this produces a harmful or toxic effect, the combination of food additives should be noted in the Annexes.

Amendment by Avril Doyle

Amendment 80

Article 10, paragraph 2

2. Where appropriate, no maximum level shall be fixed for a food additive (quantum satis). In that case, the food additive shall be used in accordance with ***good manufacturing practice, at a level not higher than is necessary to achieve the intended purpose and provided that the consumer is not misled.***

2. Where appropriate, no maximum level shall be fixed for a food additive (quantum satis). In that case, the food additive shall be used in accordance with ***the definition set out in Article 3(2)(gb).***

Or. en

Justification

See comments in respect of Article 3.2, definitions. This article should be cross-referenced to the proposed definition of “Quantum Satis” and should be amended accordingly.

Amendment by Horst Schnellhardt

Amendment 81

Article 10, paragraph 3

3. The maximum levels of use of food

3. The maximum levels of use of food

additives set out in Annex II apply to ready-to-eat foods prepared in accordance with the instructions for use unless otherwise stated.

additives set out in Annex II apply to ready-to-eat foods, ***including in a dilute state if appropriate***, prepared in accordance with the instructions for use unless otherwise stated.

Or. de

Justification

Dissolved food additives are also used in production and should be taken into account.

Amendment by Avril Doyle

Amendment 82
Article 11

A food additive falling within the scope of Regulation (EC) No 1829/2003 may be ***included in the Community lists in Annexes II and III to the present Regulation only after it has been authorised in accordance with Article 7 of Regulation (EC) No 1829/2003.***

Without prejudice to Article 4(1) and (2), a food additive falling within the scope of Regulation (EC) No 1829/2003 may be placed on the market and used in foods only when it is covered by an authorisation under Regulation (EC) No 1829/2003.

Or. en

Justification

It was understood that, under Regulation (EC) No 1829/2003, a 'one-door-one-key' procedure for the authorisation of GM derived foods and food ingredients would be adopted. The requirement for a GM derived food additive to be authorised in accordance with 1829/2003 before it may be assessed for inclusion in Annexes II and III of the proposed food additives Regulation appears to go against this approach and may result in the additive having to undergo two separate authorisation procedures. This would be excessively bureaucratic and could lead to delays.

Amendment by Carl Schlyter, Bart Staes

Amendment 83
Article 11

A food additive falling within the scope of Regulation (EC) No 1829/2003 may be included in the Community lists in Annexes II and III to *the present* Regulation only after

A food additive ***produced from, with or by GMOs or*** falling within the scope of Regulation (EC) No 1829/2003 may be included in the Community lists in Annexes

it has been authorised in accordance with Article 7 of Regulation (EC) No 1829/2003.

II and III to *this* Regulation only after it has been authorised in accordance with Article 7 of Regulation (EC) No 1829/2003. ***It shall be clearly labelled, displaying the words "produced by GMOs" or "produced from GMOs" next to its name or E-Number.***

Or. en

Justification

Food additives produced from or by genetically modified organisms or micro-organisms should be clearly labelled as such in order to guarantee the freedom of choice of consumers.

Amendment by Pilar Ayuso

Amendment 84
Article 11

*A food additive falling within the scope of Regulation (EC) No 1829/2003 may be **included in the Community lists in Annexes II and III to the present Regulation only after it has been authorised in accordance with Article 7 of** Regulation (EC) No 1829/2003*

Without prejudice to Article 4(1) and (2), a food additive falling within the scope of Regulation (EC) No 1829/2003 may be placed on the market and used in foods only when it is covered by an authorisation under Regulation (EC) No 1829/2003.

Or. en

Justification

It was understood that, under Regulation (EC) No 1829/2003, a 'one-door-one-key' procedure for the authorisation of GM derived foods and food ingredients would be adopted. The requirement for a GM derived food additive to be authorised in accordance with 1829/2003 before it may be assessed for inclusion in Annexes II and III of the proposed food additives Regulation appears to go against this approach and may result in the additive having to undergo two separate authorisation procedures. This would be excessively bureaucratic and could lead to delays.

A stream-lined procedure for authorising GM derived food additives should be ensured, in-line with the 'one-door-one-key' approach intended under Regulation (EC) No 1829/2003, that is, that when evaluation for authorisation under 1829/2003/EC and under this Regulation are required, they are both carried out jointly under one single EFSA assessment, instead of following two separate authorisation procedures.

Amendment by Åsa Westlund

Amendment 85
Article 13

Food additives shall not be used in unprocessed foods, except where such use is specially provided for in Annex II.

Food additives shall not be used in unprocessed foods, except where such use is specially provided for in Annex II. ***Additives shall not be used in unprocessed foods to make them more visually appealing or to mislead the consumer in any way as to their freshness or nutritional quality.***

Or. en

Amendment by Carl Schlyter, Bart Staes

Amendment 86
Article 14

Colours and sweeteners shall not be used in foods for infants and young children ***as referred to in*** Directive 89/398/EEC, including dietary foods for infants and young children for special medical purposes, except where specifically provided for in Annex II to *the present* Regulation.

Colours and sweeteners shall not be used in foods for infants and young children ***up to the age of 12, and foods falling within the scope of*** Directive 89/398/EEC, including dietary foods for infants and young children for special medical purposes, except where specifically provided for in Annex II to *this* Regulation.

Colours shall not be used for food marketed especially to children.

Or. en

Justification

Children can more easily be misled by food containing colours and sweeteners. This should be taken into account when authorising such additives according to the criteria given in Article 5.

Amendment by Avril Doyle

Amendment 87
Article 16, paragraph 1, point (b)

(b) in a food to which a flavouring has been

(b) in a food to which a ***food additive, food***

added, where the food additive:

(i) is permitted in the flavouring in compliance with this Regulation;

(ii) has been carried over to the food via the flavouring;

(iii) has no technological function in the final food;

enzyme or flavouring has been added, where the food additive:

(i) is permitted in the **food additive, food enzyme or** flavouring in compliance with this Regulation;

(ii) has been carried over to the food via the **food additive, food enzyme or** flavouring;

(iii) has no technological function in the final food;

Or. en

Justification

Article 16.1(b) should also include additives used in additives and enzymes (and flavourings).

Amendment by Avril Doyle

Amendment 88

Article 16, paragraph 4

4. Without prejudice to paragraph 1, the presence of **an intense** sweetener shall be permitted in a compound food with no added **sugar**, in an energy-reduced compound food, in compound dietary foods intended for low-calorie diets, and in a compound food with a long shelf-life, provided that the **intense** sweetener is permitted in one of the ingredients of the compound food.

4. Without prejudice to paragraph 1, the presence of **a** sweetener shall be permitted **only** in a compound food with no added **sugars**, in an energy-reduced compound food, in compound dietary foods intended for low-calorie diets, and in a compound food with a long shelf-life, provided that the sweetener is permitted in one of the ingredients of the compound food.

Or. en

Justification

Article 16.1 allows for the particular presence of additives under specific conditions according to the carry-over principle. As far as sweeteners are concerned, this carry-over principle is limited to even more specific conditions, as stated in Article 16.4 (and as currently laid down in Article 2a of Directive 94/35/EC on sweeteners for use in foodstuffs). Nevertheless, for clarification purposes and to avoid any differences in interpretation of the proposed provision, the word “only” should be added to paragraph 4 of Article 16.

Amendment by Åsa Westlund

Amendment 89

Article 17, introduction

Where necessary, *a* it may be decided in accordance with the procedure referred to in **Article 28(2)** as to whether or not:

Where necessary, it may be decided in accordance with the **regulatory** procedure **with scrutiny** referred to in **Article 28(2a)** whether or not:

Or. en

Justification

This amendment is needed in order to align the text to the provisions of the new comitology decision.

Amendment by Ria Oomen-Ruijten

Amendment 90

Article 19

Labelling of food additives not intended for sale to the final consumer

Food additives not intended for sale to the final consumer, whether sold singly or mixed with each other **and/or with ingredients as defined in Article 6(4) of Directive 2000/13/EC** may be marketed **only if their packaging or containers bear the information provided for in Articles 20 to 23 of this Regulation, which must be easily visible, clearly legible and indelible.**

Information to be provided for food additives **and food additive preparations** not intended for sale to the final consumer

1. Without prejudice to any other labelling requirements provided for in EU legislation or to more detailed or more extensive laws, regulations or administrative provisions regarding weights and measures or applying to the presentation, classification, packaging and labelling of dangerous substances and preparations or applying to the transport of such substances, food additives **and food additive preparations** not intended for sale to the final consumer, whether sold:

- singly or
- mixed with each other
may **only** be marketed **in compliance with the provisions of this Article.**

2. The packaging or containers, or, in the case of bulk delivery, the accompanying documents, shall provide the following information with respect to food additives intended to have a function in the food in

which they are to be used:

*(a) the name of the additive and/or its E-number laid down in this Regulation; or
(b) in the absence of a name and/or E-number, as referred to in point (a), a description of the food additive that is sufficiently precise to distinguish it from products with which it could be confused. Where food additives or food additive preparations are sold mixed with each other, the information provided for in point (a) or (b) shall be given in respect of each food additive, in descending order of its percentage by weight of the total.*

3. In addition, the following information shall be provided, either on the packaging or container, or in the documents relating to the product, which are to be supplied with or prior to the delivery:

- (a) an indication that the product is suitable for human consumption/use in food, or may be used as a food additive;*
- (b) the name or business name and address of the manufacturer or packager, or of a seller established within the Community;*
- (c) a mark identifying the batch or lot;*
- (d) if necessary, the special conditions of storage and use;*
- (e) directions for use, if the omission thereof would preclude appropriate use of the food additive;*
- (f) where applicable, sufficient information on the composition of the food additive or food additive preparation to enable the user to comply with quantitative limitations in food; where the same limit on quantity applies to a group of components used singly or in combination, the combined percentage may be given as a single figure; the limit on quantity shall be expressed either numerically or by the quantum satis principle;*
- (g) the net quantity;*
- (h) sufficient information to enable the user to comply with Directive 2000/13/EC, in particular the provisions relating to*

allergen labelling.

4. The information provided for in this Article may appear merely on the documents relating to the consignment which are to be supplied with or prior to the delivery provided that the indication "intended for the manufacture of food and not for retail sale" appears on an easily visible part of the packaging or container of the product in question.

5. The information provided for in this Article shall be given in a language easily understandable to purchasers. Within its own territory, the Member State in which the product is marketed may, in accordance with the rules of the Treaty, stipulate that this information shall be made available upon request in one or more of the official languages of the Community, to be determined by that Member State. This shall not preclude such information from being indicated in several languages.

Or. en

Justification

To create clarification and workability of the business-to-business labelling.

Amendment by Bogusław Sonik

Amendment 91

Article 19

Labelling of food additives not intended for sale to the final consumer

Food additives not intended for sale to the final consumer, whether sold singly *or* mixed with each other *and/or with ingredients as defined in Article 6(4) of Directive 2000/13/EC* may be *marketed only if their packaging or containers bear the information provided for in Articles 20 to 23 of this Regulation, which must be easily visible, clearly legible and indelible.*

Information to be provided for food additives not intended for sale to the final consumer

1. Without prejudice to any other food labelling requirements provided for in Community legislation, food additives not intended for sale to the final consumer, whether sold:

- singly,
- mixed with each other *or*
- *mixed with other substances, materials or food ingredients used to lengthen their*

storage life and facilitate their sale, standardisation, dilution, dissolution or addition to food,

may only be sold in compliance with the provisions of this Article.

2. The packaging or containers, or, in the case of bulk delivery, the accompanying documents, shall provide the following information:

(a) the function they are intended to have in the food,

(i) the name of the additive or its E-number laid down in this Regulation, or

(ii) in the absence of a name or E-number, as referred to in point (i), a description of the food additive that is sufficiently precise to distinguish it from products with which it could be confused;

(b) the net quantity;

(c) a mark identifying the batch or lot;

(d) any special conditions of storage and use;

(e) the minimum shelf life.

3. In addition, the following information shall be provided, either on the packaging or container or in the documents relating to the product, which are to be supplied with or prior to the delivery:

(a) the name or business name and address of the manufacturer or packager, or of a seller established within the Community;

(b) directions for use, if the omission thereof would preclude appropriate use of the food additive;

(c) an indication that the product is suitable for human consumption, or may be used as a food additive;

(d) an indication of the percentage share of each component subject to a limit on quantity in food or appropriate information on composition, so as to enable the user to ensure compliance with Community

provisions or, in the absence thereof, with national provisions applying to the relevant food. Where the same limit on quantity applies to a group of components used singly or in combination, the combined percentage may be given as a single figure. The limit on quantity shall be expressed either numerically or by the quantum satis principle;

(e) sufficient information to enable the user to comply with Directive 2000/13/EC, in particular the provisions relating to allergen labelling;

(f) where food additives are sold singly or mixed with each other, the information provided for in paragraph 2(a)(i) or (ii) shall be given in respect of each food additive, in descending order of its percentage by weight of the total.

Or. pl

Justification

The provisions on the labelling of food additives not intended for sale to the final consumer should be simplified. In the legislative proposal, it is not always clear whether the information required under Articles 19 to 23 should be given individually, in descending order, or together, in the form of an overall list. Articles 19 to 23 should be merged and presented in a clearer manner. Furthermore, Article 22 lays down new requirements for the labelling of food additives mixed with other food ingredients. Such additives, which are not intended for sale to the final consumer, should not come under provisions relating to the labelling of food additives. The basic information required for the labelling of finished foodstuffs is normally supplied in accompanying documents such as specifications. Article 22 should therefore be deleted. It should at the very least be possible for the information required under Article 22 to be supplied only in accompanying documents (in line with Article 21).

Amendment by Bogusław Sonik

Amendment 92
Article 20

Article deleted

Or. pl

Justification

See justification for amendment to Article 19.

Amendment by Ria Oomen-Ruijten

Amendment 93
Article 20

Article deleted

Or. en

Justification

see justification of amendment to Article 19.

Amendment by Kathy Sinnott

Amendment 94
Article 20, paragraph 1

1. Where food additives not intended for sale to the final consumer, are sold singly or mixed with each other, their packaging, or containers shall bear the ***following information*** in respect of each ***food*** additive:

(a) the name and/or its E-number laid down in this Regulation; or
(b) in the absence of a name and/or E-number, as referred to in point (a), a description of the food additive that is sufficiently precise to distinguish it from products with which it could be confused.

1. Where food additives not intended for sale to the final consumer are sold singly or mixed with each other, their packaging or containers shall bear the ***name and/or the E-number laid down in this Regulation*** in respect of each additive.

Or. en

Justification

Labelling of additives needs to include the specific name of the additive to ensure that consumers who are severely affected by a specific additive can clearly identify whether it is present in the product. If such labelling is allowed to be unclear, consumers may not be aware of the risks and face serious negative health effects.

Amendment by Kathy Sinnott

Amendment 95
Article 20, paragraph 2 a (new)

2a. Where a change in the conditions of use of a food additive increases its toxicity, its packaging or container shall bear a warning describing this change in conditions.

Or. en

Justification

The health of the consumer may be adversely affected by the condition of the use of the additive. Changes in temperature, for example, may render a substance more toxic. One example of this is Aspartame: studies have shown that when it is heated, it breaks down into several substances, some of which (such as methanol) are toxic.

Amendment by Ria Oomen-Ruijten

Amendment 96
Article 21

Article deleted

Or. en

Justification

see justification of amendment to Article 19.

Amendment by Bogusław Sonik

Amendment 97
Article 21

Article deleted

Or. en

Justification

see justification of amendment to Article 19.

Amendment by Bogusław Sonik

Amendment 98
Article 22

Article deleted

Or. en

Justification

see justification of amendment to Article 19.

Amendment by Bogusław Sonik

Amendment 99
Article 23

Article deleted

Or. en

Justification

see justification of amendment to Article 19.

Amendment by Carl Schlyter, Bart Staes

Amendment 100
Article 23, paragraph 1, point (c)

(c) instructions for use, if the omission thereof would **preclude** appropriate use of the food additive;

(c) instructions for use, if the omission thereof would **impede** appropriate use of the food additive;

Or. en

Justification

The requirement for instructions of use should be more explicit.

Amendment by Horst Schnellhardt

Amendment 101

Article 23, paragraph 1, point (h) a (new)

(ha) the date of minimum durability;

Or. de

Justification

The expiry date should not only be indicated at the point of sale to the final consumer but in general in order to guarantee maximum protection of consumers and users.

Amendment by Horst Schnellhardt

Amendment 102

Article 23, paragraph 2

2. By way of derogation from paragraph 1, the information required in points (c) to (f) and point **(h)** of that paragraph may appear merely on the documents relating to the consignment which are to be supplied with or prior to the delivery, provided that the indication “intended for the manufacture of food and not for retail sale” appears on an easily visible part of the packaging or container of the product in question.

2. By way of derogation from paragraph 1, the information required in points (c) to (f) and point **(ha)** of that paragraph may appear merely on the documents relating to the consignment which are to be supplied with or prior to the delivery, provided that the indication “intended for the manufacture of food and not for retail sale” appears on an easily visible part of the packaging or container of the product in question.

Or. de

Justification

Necessitated by the amendment to Paragraph 1.

Amendment by David Martin, Åsa Westlund

Amendment 103

Article 23, paragraph 2 a (new)

2a. By way of derogation from the labelling and information requirements of Articles 19 to 22, and of paragraph 1 of this Article, for bulk deliveries all of the information

may appear on the accompanying documents which are to be supplied with or prior to the delivery.

Or. en

Justification

The current proposal makes no allowance for industrial supply of additives in tankers where information requirements are different from packages and containers.

Amendment by John Bowis

Amendment 104
Article 23, paragraph 2 a (new)

2a. By way of derogation from the labelling and information requirements of Articles 19 to 22, and of paragraph 1 of this Article, for bulk deliveries all of the information may appear on the accompanying documents which are to be supplied with or prior to the delivery.

Or. en

Justification

The current proposal makes no allowance for industrial supply of additives in tankers where information requirements are different from packages and containers.

Amendment by Horst Schnellhardt

Amendment 105
Article 24, paragraph 1, introduction

1. Without prejudice to Directive 2000/13/EC, food additives intended for sale to the final consumer may be marketed only if their packaging contains the following information, ***which must be easily visible, clearly legible and indelible:***

1. Without prejudice to Directive 2000/13/EC, food additives intended for sale to the final consumer may be marketed only if their packaging contains the following information:

Or. de

Justification

The requirements are unclear. The value of the provisions of the labelling directive has been proven in the past, and they do not require any additional, bureaucratic supplement.

Amendment by Ria Oomen-Ruijten

Amendment 106
Article 24, paragraph 1, point (a)

(a) the name under which the food additive is sold; that name shall be constituted by the name laid down by any Community provisions applying to the food additive in question **and** its E-number;

(a) the name under which the food additive is sold; that name shall be constituted by the name laid down by any Community provisions applying to the food additive in question **or** its E-number;

Or. en

Justification

Food labelling Directive 2000/13/EC, Article 6, states that ingredients belonging to one of the categories listed in Annex II (food additives, including sweeteners) "must be designated by the name of that category, followed by their specific name or EC number". To create consistency, legal certainty and to avoid consumer confusion, this legislation should be in line with the provisions of the food labelling Directive.

Amendment by Carl Schlyter, Bart Staes

Amendment 107
Article 24, paragraph 3

3. The labelling of a table-top sweetener containing polyols and/or aspartame and or aspartame-acesulfame salt shall bear the following warnings:

(a) polyols: '**excessive** consumption may induce laxative effects';

(b) aspartame/aspartame-acesulfame salt: 'contains a source of phenylalanine'.

3. The labelling of a table-top sweetener **and other food** containing polyols and/or aspartame and or aspartame-acesulfame salt shall bear the following warnings:

(a) polyols: 'consumption may induce laxative effects';

(b) aspartame/aspartame-acesulfame salt: 'contains a source of phenylalanine'.

Or. en

Justification

The labelling requirements should be extended to all sources of polyols and aspartame. The words “excessive consumption” would incite consumers to disregard the warning.

Amendment by Carl Schlyter, Bart Staes

Amendment 108
Article 24, paragraph 3 a (new)

3a. The labelling of food containing azo-dyes shall bear the warning ‘azo-dyes may provoke allergenic effects’.

Or. en

Justification

Azo-Dyes can provoke allergenic reactions. Therefore a clear warning should be required by the regulation.

Amendment by Bogusław Sonik

Amendment 109
Article 25

Article deleted

Or. en

Justification

see justification of amendment to Article 19.

Amendment by Ria Oomen-Ruijten

Amendment 110
Article 25

Article deleted

Or. en

Justification

see justification of amendment to Article 19.

Amendment by Horst Schnellhardt

Amendment 111
Article 26, paragraph 1

1. A producer or user of a food additive shall inform the Commission immediately of **any new** scientific or technical information which might affect the assessment of the safety of the food additive.

1. A producer or user of a food additive shall inform the Commission immediately of scientific **data** or technical information **known and available to him** which might affect the assessment of the safety of the food additive.

Or. de

Justification

Producers of food additives normally do not have data on the actual use made of additives. Customers may use substances in various fields or food categories.

Amendment by Ria Oomen-Ruijten

Amendment 112
Article 26, paragraph 2

2. **A producer or user** of a food additive shall, **at the request of** the Commission, **inform it of** the actual use of the food additive.

2. **Producers and users** of a food additive shall **cooperate with** the Commission **in obtaining data regarding** the actual use of the food additive. **The information provided shall be kept confidential.**

Or. en

Justification

Producers and users of food additives, as key players in the food chain, have various data available to them. Both producers and users should cooperate to assist the Commission in trying to compile data on the actual use of a food additive. This particular information, however should be kept confidential in order to prevent potential harm to commercial interests or interests on scientific research and development.

Amendment by Horst Schnellhardt

Amendment 113
Article 26, paragraph 2

2. A producer or user of a food additive shall, at the request of the Commission, inform it of the actual use of the food additive.

2. A producer or user of a food additive shall, at the request of the Commission, inform it of the actual use of the food additive, ***insofar as the data are available to him. The information provided shall be treated as confidential.***

Or. de

Justification

Producers of food additives normally do not have data on the actual use made of additives. Customers may use substances in various fields or food categories. Moreover, the information provided - particularly if it relates to production quantities - constitutes trade secrets and should therefore be treated as confidential.

Amendment by Horst Schnellhardt

Amendment 114
Article 27, paragraph 1

1. Member States shall maintain systems to monitor the consumption and use of food additives and report their findings ***each year*** to the Commission and the European Food Safety Authority (hereinafter referred to as the 'Authority').

1. Member States shall maintain systems to monitor the consumption and use of food additives, ***adopting a risk-based approach,*** and report their findings ***at appropriate intervals*** to the Commission and the European Food Safety Authority (hereinafter referred to as the 'Authority').

Or. de

Justification

Particularly for small and medium-sized enterprises, the requirement to report annually is too bureaucratic and impractical. Its advantages are not obvious, either, as it would hardly be possible to process the findings. It seems more worthwhile for monitoring to concentrate on risks and on the problems which might arise.

Amendment by John Bowis

Amendment 115
Article 27, paragraph 1

1. Member States shall maintain systems to monitor the consumption and use of food additives and report their findings each year to the Commission and the European Food Safety Authority (hereinafter referred to as the ‘Authority’).

1. Member States shall maintain systems to monitor the consumption and use of food additives ***on a risk-based approach*** and report their findings each year to the Commission and the European Food Safety Authority (hereinafter referred to as the ‘Authority’).

Or. en

Justification

It is important to target resources to where they can be of most benefit. Monitoring should be targeted to those additives where there is a greater risk of consumption exceeding acceptable daily intakes.

Amendment by Anja Weisgerber

Amendment 116
Article 27, paragraph 1

2. Member States shall maintain systems to monitor the consumption and use of food additives and report their findings ***each year*** to the Commission and the European Food Safety Authority (hereinafter referred to as the ‘Authority’).

2. Member States shall maintain systems to monitor the consumption and use of food additives, ***adopting a risk-based approach,*** and report their findings ***at appropriate intervals*** to the Commission and the European Food Safety Authority (hereinafter referred to as the ‘Authority’).

Or. de

Justification

Particularly for small and medium-sized enterprises, the requirement to report annually is too bureaucratic and impractical. Its advantages are not obvious, either, as it would hardly be possible to process the findings. It seems more worthwhile for monitoring to concentrate on risks and on the problems which might arise.

Amendment by Kathy Sinnott

Amendment 117
Article 27, paragraph 1

1. Member States shall maintain systems to monitor the consumption and use of food additives and report their findings each year to the Commission and the European Food Safety Authority (hereinafter referred to as the ‘Authority’).

1. Member States shall maintain systems to monitor the consumption and use of food additives, ***and specifically consumption and use among pregnant women, infants and children***, and report their findings each year to the Commission and the European Food Safety Authority (hereinafter referred to as the ‘Authority’).

Or. en

Justification

Certain additives have very different health effects on infants and children as their bodies develop and grow. MSG and other excitotoxins for example have been shown by studies to have neurodegenerative effects.

Amendment by Åsa Westlund

Amendment 118
Article 27, paragraph 2

2. After the Authority has been consulted, a common methodology for the gathering of information by the Member States on dietary intake of food additives in the Community may be adopted in accordance with the procedure referred to in ***Article 28(2)***.

2. After the Authority has been consulted, a common methodology for the gathering of information by the Member States on dietary intake of food additives in the Community may be adopted in accordance with the ***regulatory*** procedure ***with scrutiny*** referred to in ***Article 28(2a)***.

Or. en

Justification

This amendment is needed in order to align the text to the provisions of the new comitology decisions.

Amendment by Carl Schlyter, Bart Staes

Amendment 119
Article 27, paragraph 2

2. After the Authority has been consulted, a common methodology for the gathering of information by the Member States on dietary intake of food additives in the Community may be adopted in accordance with the procedure referred to in **Article 28(2)**.

2. After the Authority has been consulted, a common methodology for the gathering of information by the Member States on dietary intake of food additives in the Community may be adopted in accordance with the **regulatory** procedure **with scrutiny** referred to in **Article 28(2a)**.

Or. en

Justification

The new comitology procedure with scrutiny has to be applied for establishing the methodology for an effective monitoring provision.

Amendment by Mojca Drčar Murko

Amendment 120
Article 27, paragraph 2

2. After the Authority has been consulted, a common methodology for the gathering of information by the Member States on dietary intake of food additives in the Community **may** be adopted in accordance with the procedure referred to in Article 28(2).

2. After the Authority has been consulted, a common methodology for the gathering of information by the Member States on dietary intake of food additives in the Community **shall** be adopted in accordance with the procedure referred to in Article 28(2).

Or. en

Justification

A common methodology is needed in order to ensure that the data collected can be compared.

Amendment by Åsa Westlund

Amendment 121
Article 30, paragraph 1

1. Food additives which were permitted for use in foods under Directives 94/35/EC,

1. Food additives which were permitted for use in foods under Directives 94/35/EC,

94/36/EC and 95/2/EC before the date of entry into force of this Regulation and their conditions of use shall be entered in Annex II to the present Regulation after a review of their compliance with Articles 5, 6 and 7 of the present Regulation **in accordance with the procedure referred to in Article 28(2)**. This review shall not include a new risk assessment carried out by the Authority. The review shall be completed by [...]

94/36/EC and 95/2/EC before the date of entry into force of this Regulation and their conditions of use shall be entered in Annex II to the present Regulation after a review of their compliance with Articles 5, 6 and 7 of the present Regulation. This review shall not include a new risk assessment carried out by the Authority. The review shall be completed by [...]

Or. en

Justification

This amendment is needed in order to keep under codecision any modification to the Annexes of this Regulation.

Amendment by Åsa Westlund

Amendment 122

Article 30, paragraph 1

1. Food additives which were permitted for use in foods under Directives 94/35/EC, 94/36/EC and 95/2/EC before the date of entry into force of this Regulation and their conditions of use shall be entered in Annex II to the present Regulation after a review of their compliance with Articles 5, 6 and 7 of the present Regulation in accordance with the procedure referred to in **Article 28(2)**. This review shall not include a new risk assessment carried out by the Authority. The review shall be completed by [...]

1. Food additives which were permitted for use in foods under Directives 94/35/EC, 94/36/EC and 95/2/EC before the date of entry into force of this Regulation and their conditions of use shall be entered in Annex II to the present Regulation after a review of their compliance with Articles 5, 6 and 7 of the present Regulation in accordance with the **regulatory procedure with scrutiny** referred to in **Article 28(2a)**. This review shall not include a new risk assessment carried out by the Authority. The review shall be completed by [...]

Or. en

Justification

This amendment is needed in order to align the text to the provisions of the new comitology decisions.

Amendment by Carl Schlyter, Bart Staes

Amendment 123
Article 30, paragraph 1

1. Food additives which were permitted for use in foods under Directives 94/35/EC, 94/36/EC and 95/2/EC before the date of entry into force of this Regulation and their conditions of use shall be entered in Annex II to the present Regulation after a review of their compliance with **Articles 5, 6 and 7 of** the present Regulation in accordance with the procedure referred to in **Article 28(2)**. This review shall **not** include a new risk assessment carried out by the Authority. The review shall be completed by [...]

1. Food additives which were permitted for use in foods under Directives 94/35/EC, 94/36/EC and 95/2/EC before the date of entry into force of this Regulation and their conditions of use shall be entered in Annex II to the present Regulation after a review of their compliance with the present Regulation in accordance with the **regulatory procedure with scrutiny** referred to in **Article 28(2a)**. This review shall include a new risk assessment carried out by the Authority. The review shall be completed by [...]

Or. en

Justification

The new comitology procedure with scrutiny has to be applied for the review process. Compliance with all requirements of the new regulation has to be verified.

Amendment by Åsa Westlund

Amendment 124
Article 30, paragraph 2

2. Food additives authorised for use in food additives as permitted carriers in Annex V to Directive 95/2/EC and their conditions of use shall be entered in Annex III, Part 1 to this Regulation after a review of their compliance with Article 5 of this Regulation **in accordance with the procedure laid down in Article 28(2)**. This review shall not include a new risk assessment carried out by the Authority. The review shall be completed by [.....].

2. Food additives authorised for use in food additives as permitted carriers in Annex V to Directive 95/2/EC and their conditions of use shall be entered in Annex III, Part 1 to this Regulation after a review of their compliance with Article 5 of this Regulation. This review shall not include a new risk assessment carried out by the Authority. The review shall be completed by [.....].

Or. en

Justification

This amendment is needed in order to keep under codecision any modification to the Annexes

of this Regulation.

Amendment by Åsa Westlund

Amendment 125
Article 30, paragraph 2

2. Food additives authorised for use in food additives as permitted carriers in Annex V to Directive 95/2/EC and their conditions of use shall be entered in Annex III, Part 1 to this Regulation after a review of their compliance with Article 5 of this Regulation in accordance with the procedure laid down in **Article 28(2)**. This review shall not include a new risk assessment carried out by the Authority. The review shall be completed by [.....].

2. Food additives authorised for use in food additives as permitted carriers in Annex V to Directive 95/2/EC and their conditions of use shall be entered in Annex III, Part 1 to this Regulation after a review of their compliance with Article 5 of this Regulation in accordance with the **regulatory** procedure **with scrutiny** referred to in **Article 28(2a)**. This review shall not include a new risk assessment carried out by the Authority. The review shall be completed by [.....].

Or. en

Justification

This amendment is needed in order to align the text to the provisions of the new comitology decisions.

Amendment by Åsa Westlund

Amendment 126
Article 30, paragraph 4

4. Any appropriate transitional measures may be adopted in accordance with the procedure laid down in **Article 28(2)**.

4. Any appropriate transitional measures may be adopted in accordance with the **regulatory** procedure **with scrutiny** referred to in **Article 28(2a)**.

Or. en

Justification

This amendment is needed in order to align the text to the provisions of the new comitology decisions.

Amendment by Ria Oomen-Ruijten

Amendment 127

Article 31, paragraph 1

1. Food additives which were *permitted before the date of entry into force of this Regulation* shall be subject to a new risk assessment carried out by the Authority.

1. Food additives which were *on the market at the date of entry into force of this Regulation, but have not been reviewed and received a positive opinion from the Scientific Committee on Foods or the Authority* shall be subject to a new risk assessment carried out by the Authority. *These additives will be allowed on the market until the new risk assessment is carried out by the Authority.*

Or. en

Justification

Procedures for elaborate safety assessments that are based on the latest scientific knowledge, have been in place in the EU since the early nineties. Most of the additives marketed today have gone through this safety evaluation and are found to be safe. Food additives that have gone through a complete safety review under the previous legislation and consumed to a significant degree before the entry of this Regulation, and where no safety concerns have been raised, should be allowed on the market until the new risk assessment is carried out by the Authority.

Amendment by Åsa Westlund

Amendment 128

Article 31, paragraph 2

2. The Authority's risk evaluation shall form part of the review to be carried out by the Commission, assisted by the Committee, of all food additives which were approved prior to the entry into force of this Regulation. This review shall be conducted on the basis of the conditions of authorisation laid down in this Regulation, and on the basis of an assessment of intake and risk management.

All food additives that are to continue to be authorised in the Community shall be transferred to the Community lists in

Annexes II and III to this Regulation. Annex III to this Regulation should be completed with the other food additives used in food additives and enzymes and their conditions of use in accordance with Regulation (EC) No [...] establishing a common authorisation procedure for food additives, food enzymes and food flavourings. To allow a suitable transition period, the provisions in Annex III, other than the provisions concerning carriers for food additives, should not apply until [1.1.2011].

2. After consultation of the Authority, an evaluation programme for those additives shall be adopted within one year after the date of entry into force of this Regulation, in accordance with the procedure laid down in Article 28(2). The evaluation programme shall be published in the Official Journal of the European Union.

The review shall be conducted on the basis of an evaluation programme which shall be adopted, after consultation of the Authority, within one year after the date of entry into force of this Regulation. The evaluation programme shall be published in the Official Journal of the European Union.

Or. en

Justification

This amendment is needed in order to keep under codecision any modification to the Annexes of this Regulation.

Amendment by Horst Schnellhardt

Amendment 129
Article 34, subparagraph 3 a (new)

Foods which do not accord with the requirements of this Regulation but have been produced in accordance with Community law may still be marketed for the duration of their shelf-life.

Or. de

Justification

As the regulation partly includes new or supplementary labelling requirements for food additives, adequate transitional provisions are needed.

Amendment by Ria Oomen-Ruijten

Amendment 130
Annex I, point 5

5. 'carriers', are substances used to dissolve, dilute, disperse or otherwise physically modify a food additive or a flavouring **or** food enzyme without altering its function (and without exerting any technological effect themselves) in order to facilitate its handling, application or use;

5. 'carriers' are substances used to dissolve, dilute, disperse or otherwise physically modify a food additive or a flavouring, food enzyme, ***nutrient and/or other substance added for nutritional or physiological purposes to a foodstuff (or food and/or food supplement)*** without altering its function (and without exerting any technological effect themselves) in order to facilitate its handling, application or use;

Or. en

Justification

1. Carriers (food additives and/or food ingredients) are very often needed to facilitate the handling for the use of nutrients in foods and food supplements. This technological need is similar to food additives and flavourings that are also used at low levels.

2. A harmonization on permitted carriers for nutrient preparations is needed with respect to recent regulatory developments on food supplements and food fortification.

Amendment by Horst Schnellhardt

Amendment 131
Annex I, point 5

5. 'carriers', are substances used to dissolve, dilute, disperse or otherwise physically modify a food additive **or** a flavouring **or** food enzyme without altering its function (and without exerting any technological effect themselves) in order to facilitate its handling, application or use;

5. 'carriers' are substances used to dissolve, dilute, disperse or otherwise physically modify a food additive, a flavouring, **a** food enzyme, ***a nutrient or another substance with a nutritional or physiological effect*** without altering its function (and without exerting any technological effect themselves) in order to facilitate its handling, application or use;

Or. de

Justification

Carriers are not only used in conjunction with food additives, flavourings and enzymes, but also for nutrients and other substances with a nutritional or physiological effect. In connection with the general standard for food additives laid down in the Codex Alimentarius, an addition to the definition is likewise currently being debated.

Amendment by Mojca Drčar Murko

Amendment 132
Annex I, point 5

5. 'carriers', are substances used to dissolve, dilute, disperse or otherwise physically modify a food additive or a flavouring **or** food enzyme without altering its function (and without exerting any technological effect themselves) in order to facilitate its handling, application or use;

5. 'carriers', are substances used to dissolve, dilute, disperse or otherwise physically modify a food additive or a flavouring, food enzyme, **nutrient and/or other substance added for nutritional or physiological purposes to a foodstuff (or food and/or food supplement)** without altering its function (and without exerting any technological effect themselves) in order to facilitate its handling, application or use;

Or. en

Justification

For the use of nutrients in food and food supplements very often carriers are needed to facilitate the handling. This technological need is similar to food additives and flavourings that are also used at low levels. A harmonization on permitted carriers for nutrient preparations is needed with respect to regulatory developments on food supplements and food fortification.

Amendment by Horst Schnellhardt

Amendment 133
Annex III, Title

Community list of food additives approved for use in food additives **and** food enzymes, and conditions of use.

Community list of food additives approved for use in food additives, food enzymes **and food flavourings**, and conditions of use.

Or. de

Justification

In the interests of comprehensive and stringent legislation, flavourings should be specifically mentioned.

Amendment by Horst Schnellhardt

Amendment 134
Annex III, Part 3 a (new)

Part 3 a Additives in food flavourings

Or. de

Justification

In the interests of comprehensive and stringent legislation, flavourings should be included.

Amendment by Horst Schnellhardt

Amendment 135
Annex III, Part 3 b (new)

Part 3 b Carriers in nutrients

Or. de

Justification

In the interests of comprehensive and stringent legislation, carriers should be included.