EUROPEAN PARLIAMENT

2004 *2009*

Session document

FINAL
A6-0154/2007

20.4.2007

***I
REPORT

on the proposal for a regulation of the European Parliament and of the Council on food additives
(COM(2006)0428 – C6-0260/2006 – 2006/0145(COD))

Committee on the Environment, Public Health and Food Safety

Rapporteur: Åsa Westlund

PR_COD_1am

Symbols for procedures

*	Consultation procedure *majority of the votes cast*
**I	Cooperation procedure (first reading) *majority of the votes cast*
**II	Cooperation procedure (second reading) *majority of the votes cast, to approve the common position* *majority of Parliament's component Members, to reject or amend the common position*
***	Assent procedure *majority of Parliament's component Members except in cases covered by Articles 105, 107, 161 and 300 of the EC Treaty and Article 7 of the EU Treaty*
***I	Codecision procedure (first reading) *majority of the votes cast*
***II	Codecision procedure (second reading) *majority of the votes cast, to approve the common position* *majority of Parliament's component Members, to reject or amend the common position*
***III	Codecision procedure (third reading) *majority of the votes cast, to approve the joint text*

(The type of procedure depends on the legal basis proposed by the Commission.)

Amendments to a legislative text

In amendments by Parliament, amended text is highlighted in ***bold italics***. Highlighting in *normal italics* is an indication for the relevant departments showing parts of the legislative text for which a correction is proposed, to assist preparation of the final text (for instance, obvious errors or omissions in a given language version). These suggested corrections are subject to the agreement of the departments concerned.

CONTENTS

Page

DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

on the proposal for a regulation of the European Parliament and of the Council on food additives
(COM(2006)0428 – C6-0260/2006 – 2006/0145(COD))

(Codecision procedure: first reading)

The European Parliament,

– having regard to the Commission proposal to the European Parliament and the Council (COM(2006)0428)[1],

– having regard to Article 251(2) and Article 95 of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C6-0260/2006),

– having regard to the opinion of the Committee on Legal Affairs on the proposed legal basis,

– having regard to Rules 51 and 35 of its Rules of Procedure,

– having regard to the report of the Committee on the Environment, Public Health and Food Safety (A6-0154/2007),

1. Approves the Commission proposal as amended;

2. Calls on the Commission to refer the matter to Parliament again if it intends to amend the proposal substantially or replace it with another text;

3. Instructs its President to forward its position to the Council and Commission.

Text proposed by the Commission	Amendments by Parliament
Amendment 1 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 the environment,*** and the interests of consumers***, including those consumers who are intolerant to certain substances,*** via

[1] OJ C ... / Not yet published in OJ.

comprehensive and streamlined procedures.

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 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 2
Recital 6

(6) Substances not consumed as food itself but used intentionally in the processing of foods, which ***only*** remain as residues in the final food and do not have a technological effect in the final product (processing aids), should not be covered by this Regulation.	(6) Substances not consumed as food itself but used intentionally in the processing of foods, which ***do not*** remain as residues in the final food and do not have a technological effect in the final product (processing aids), should not be covered by this Regulation.

Justification

It is of no significance to consumer health whether a substance has been used as a processing aid or an additive. The decisive factor is whether it remains in the final product or not. Naturally, a long transitional period is required before processing aids and additives, as defined at the present time, will need to be authorised in accordance with this Regulation.

Amendment 3
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 use 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 use 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***.

Justification

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

Amendment 4
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.

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 5
Recital 14

(14) Food additives should be kept under continuous observation and must be re-evaluated whenever necessary in the light of changing conditions of use and new scientific information.	(14) Food additives should be kept under continuous observation and must be re-evaluated whenever necessary in the light of changing conditions of use and new scientific information. ***Special evaluation programmes should be adopted to review authorisations granted.***

Justification

Authorisation for the use of additives must be reviewed continually. Additives should be ranked in order of priority according to the urgency of reviewing their use. This priority ranking should be drawn up by means of an evaluation programme so that it is clear to all parties involved. This does not prevent the Commission and/or EFSA, however, from taking

the initiative to review certain substances more promptly.

Amendment 6
Recital 21

(21) Following the adoption of this Regulation the Commission assisted by the Standing Committee on Food Chain and Animal Health should review all the existing authorisations ***for criteria, other than safety, such as intake, technological need and the potential to mislead the consumer***. All food additives that are to continue to be authorised in the Community should 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].	(21) Following the adoption of this Regulation the Commission, assisted by the Standing Committee on Food Chain and Animal Health, should review all the existing authorisations ***on the basis of the conditions for authorisation laid down in this Regulation***. All food additives that are to continue to be authorised in the Community should 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].

Justification

There is no need to list here the criteria for authorisation pursuant to this Regulation.

Amendment 7
Article 1, paragraph 1

This Regulation lays down rules on food additives used in foods to ensure the effective functioning of the internal market and a high level of human health ***protection*** and consumer protection.	This Regulation lays down rules on food additives used in foods to ensure the effective functioning of the internal market and a high level of human health, consumer ***and environmental*** protection.

Justification

In accordance with the Cardiff Process, environmental aspects must be integrated into all EU

legislation. What a person eats does not stay in the human body but is dispersed into the natural environment and becomes part of the natural cycle. Even if a substance does not entail any health risk to the person consuming the product which contains the substance, there may be negative effects on the environment and public health at subsequent stages, which should be taken into account when deciding to grant authorisation or not. A sound environment must therefore also be one of the aims of the Regulation.

Amendment 8
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 Regulation (EC) No*** .../... ***[on food enzymes] and including food flavourings as referred to in Regulation (EC) No .../.... [on food flavourings and certain food ingredients with flavouring properties];***

Justification

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

Amendment 9
Article 1 a (new)

	Article 1a
	Foodstuffs which contain additives that do not comply with this Regulation shall not be placed on the market.

Justification

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

Amendment 10
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;

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 11
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.

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 12
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.

Justification

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

Amendment 13
Article 3, paragraph 2, point (a), introductory part

(a) 'food additive' shall mean any substance not normally consumed as a food in itself and not normally used as a characteristic	(a) 'food additive' shall mean any substance not normally consumed as a

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:	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:

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 14
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;

Justification

Since mono- and disacharides (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 15
Article 3, paragraph 2, point (a) (ii)

(ii) foods, whether dried or in concentrated	(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;	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***;

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 16
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;

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 17
Article 3, paragraph 2, point (b) (iii)

(iii) ***may result in the unintentional but technically unavoidable presence*** in the final product ***of residues of the substance or its derivatives provided they do not present any health risk and do not have any technological effect on the final product***;	(iii) ***does not remain*** in the final product;

Justification

It is of no significance to consumer health whether a substance has been used as a processing aid or an additive. The decisive factor is whether it remains in the final product or not. Naturally, a long transitional period is required before processing aids and additives, as defined at the present time, will need to be authorised in accordance with this Regulation.

Amendment 18
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;

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 19
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 to the final consumer as a substitute for ***sugar***.	(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 ***sugars***.

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 20
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.

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 dissacharides 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 21
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 misled[1].

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

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 22
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 additive does not comply with the requirements of this Regulation.

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 23
Article 5, paragraph 1, point (a a) (new)

(aa) it does not, on the basis of the scientific evidence available, adversely affect public health or the health of vulnerable groups during any part of its life cycle;

Justification

Even if a substance does not entail any health risk to the person consuming the product which contains the substance, there may be negative effects on the environment and public health at subsequent stages, which should be taken into account when deciding to grant authorisation or not. The use of antibiotics in food and its implications for the development of resistance is one example.

Amendment 24
Article 5, paragraph 1, point (b)

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

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 25
Article 5, paragraph 1, point (c b) (new)

(cb) it does not, on the basis of the scientific evidence available, entail any adverse environmental effects during any part of its life cycle.

Justification

According to the Cardiff process, environmental aspects must be integrated into all EU legislation. What a person eats does not stay in the human body but is dispersed into the natural environment and becomes part of the natural cycle.

Amendment 26
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***;

Amendment 27
Article 5, paragraph 3, point (a)

(a) the food does not constitute a significant component of a normal diet; or	***deleted***

Justification

Lowering the quality of a food can never be to the benefit of consumers, except in the case of point (b).

Amendment 28
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 shall refer explicitly and transparently to the consideration given to the criteria laid down in paragraphs 1 to 3, and shall explain the basis for the final decision.

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 29
Article 6, point (a)

(a) replacing sugars for the production of energy-reduced food, non-cariogenic	(a) replacing sugars for the production of energy-reduced food, non-cariogenic

food or food with no added sugars;	food, ***food reduced in sugars*** or food with no added sugars;

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 30
Article 7, paragraph 1 a (new)

There must, however, be no risk of the additive misleading consumers into believing that the food contains ingredients other than those actually present.

Justification

Consumers are sometimes misled by the use of additives despite the fact that one of the criteria for authorisation under previous legislation is that consumers must not be misled. For example, consumers are sometimes duped into believing that a product contains a certain fruit through the use of a particular colour for the product. Consumer protection must therefore be strengthened in this regard.

Amendment 31
Article 7 a (new)

Article 7a

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.

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 32
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.

Justification

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

Amendment 33
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;

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 in additives /enzymes/ flavourings).

Amendment 34
Article 9, paragraph 2, point (d a) (new)

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

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 35
Article 10, paragraph 1 a (new)

	1a. If the use of nanotechnology is authorised, separate limit values for that purpose shall be laid down in accordance with paragraph 1(a).

Justification

There is currently little known about the health risks of nanotechnology. It is not certain that the limit value for traditional use of an additive and the limit value for nanoparticles of an additive should be the same.

Amendment 36
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).***

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 37
Article 10, paragraph 3

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.	3. The maximum levels of use of food 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.

Justification

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

Amendment 38
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.	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 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.***

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 39
Article 16, paragraph 1, point (b)

(b) in a food to which a flavouring has been added, where the food additive:	(b) in a food to which a ***food additive, food enzyme or*** flavouring has been added, where the food additive:
(i) is permitted in the flavouring in compliance with this Regulation;	(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 flavouring;	(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;	(iii) has no technological function in the final food;

Justification

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

Amendment 40
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:

Justification

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

Amendment 41
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.

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 42
Article 23, paragraph 1, point (h a) (new)

(ha) the date of minimum durability.

Justification

Das Haltbarkeitsdatum sollte nicht nur bei der Abgabe an den Endverbraucher, sondern generell angegeben werden, um ein Höchstmaß an Verbraucher- und Anwenderschutz zu garantieren.

Amendment 43
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 ***points*** (h) ***and (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.

Amendment 44
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.

Justification

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

Amendment 45
Article 24, paragraph 3 a (new)

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

Justification

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

Amendment 46
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').

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 47
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 ***regulatory*** procedure ***with scrutiny*** referred to in ***Article 28(2a)***.

Justification

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

Amendment 48
Article 28, paragraph 2 a (new)

	2a. Where reference is made to this paragraph, Article 5a (1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

Justification

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

Amendment 49
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	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 *this* Regulation after a review of their compliance with Articles 5, 6 and 7 of *this* Regulation. This review shall not include a new risk assessment carried out by the Authority. The review shall be completed by

review shall be completed by […]	[…]

Justification

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

Amendment 50
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 [….].

Justification

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

Amendment 51
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)***.

Justification

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

Amendment 52
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	1. Food additives which were ***on the market at the date of entry into force of this Regulation, but have not been***

assessment carried out by the Authority.	*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 to remain on the market until the new risk assessment is carried out by the Authority.*

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 53
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. Annex III 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.

Justification

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

Amendment 54
Article 31, paragraph 2 a (new)

	2a. After the evaluation programme in paragraph 2 has been carried out, and after consultation of the Authority, a new evaluation programme shall be adopted for authorisations pursuant to this Regulation. This new evaluation programme shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 28(2a) and shall be published in the Official Journal of the European Union.

Justification

There should also be a rolling review in the future. It is important that this is put on a formal footing at the same time as giving the EFSA scope to rank food additives according to the urgency of reviewing their use.

Amendment 55
Article 31, paragraph 2 b (new)

	2b. Food additives and uses which are no longer current shall be removed from the Annexes when the authorisation is

reviewed.

Justification

This is required so that the Community list is up to date and provides correct information to consumers.

Amendment 56
Article 34, paragraph 3 a (new)

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

Justification

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

Amendment 57
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;

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 58

Annex III

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.
Part 1 Carriers in food additives	Part 1 Carriers in food additives***, food enzymes and food flavourings***
Part 2 Additives other than carriers in food additives	Part 2 Additives other than carriers in food additives***, food enzymes and food flavourings***
Part 3 Additives in food enzymes	

Justification

To be consistent with Article 16, Annex III must include both authorised carriers and authorised other additives in food additives, food enzymes and food flavourings.

Amendment 59
Annex III, Part 3 a (new)

Part 3 a Additives in food flavourings

Justification

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

Amendment 60
Annex III, Part 3 b (new)

Part 3 b Carriers in nutrients

Justification

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

EXPLANATORY STATEMENT

The Commission has proposed that, in future, decisions on authorisation of food additives should be taken by way of the comitology procedure. Your rapporteur can see advantages in this respect but only if the considerations which the European Parliament has often raised over the years is clearly reflected in the new Regulation on food additives and the new Regulation on a common authorisation procedure for food additives, food enzymes and food flavourings. These considerations primarily relate to the environment, public health and allergy sufferers.

The new Regulation on food additives should also be strengthened in terms of the requirements relating to procedural transparency, the review of authorisations for food additives and clarification of what might be misleading to consumers. In addition, there should be a redefinition of what constitutes a food additive or a processing aid, and the use of nanotechnology should be regulated.

Considerations relating to the environment, public health and the range of products available to allergy sufferers

In accordance with the Cardiff Process, environmental aspects must be integrated into all EU legislation. This is particularly relevant in this legislation as what a person eats does not stay in the human body but is dispersed into the natural environment and becomes part of the natural cycle. Even if a substance does not entail any health risk to the person consuming the product which contains the substance, there may be negative effects on the environment and public health at subsequent stages, which should be taken into account when deciding to grant authorisation or not. The use of antibiotics in food and its implications for the development of resistance to antibiotics is one example of what may have damaging effects on public health. When an additive is considered for authorisation, the criteria must include that it does not have negative effects on either public health or the environment. A sound environment should also be one of the aims of the Regulation.

Allergy sufferers are greatly helped by the fact that products containing common allergenic substances must be labelled, though this does not go far enough. Vulnerable groups and allergy sufferers should be given particular consideration. 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 that the substance or its use does not reduce the range of foods available to allergy sufferers.

Your rapporteur proposes, however, that even where an additive may adversely affect public health, the environment or the range of products available to allergy sufferers adversely, it should be possible to authorise it, if the advantages to consumers obviously outweigh the disadvantages.

If, on the basis of the criteria laid down in Article 5, there are better alternatives to the additive and it is economically reasonable to use the alternative, then the use of the additive in

question should not be authorised. It may be a question, for example, of using a different production method which does not require the use of additives or there may be already authorised additives which are better within the terms of the criteria laid down in Article 5.

Transparency and review

Authorisations for use of additives must be subject to rolling review. Your rapporteur proposes that all current authorisations should be reviewed on the basis of the new criteria before they are transferred to the new Community list. Thereafter, the rolling review of authorisations should continue by way of a transparent procedure in accordance with an evaluation programme to be adopted by comitology procedure. The evaluation programme should be based on a priority system whereby additives are ranked according to the urgency of reviewing their use. This priority ranking should be drawn up by means of an evaluation programme so that it is clear to all parties involved. The evaluation programme must not however prevent the Commission and/or the EFSA from taking initiatives to review certain authorisations more promptly.

Consumer considerations

One of the already existing criteria for authorisation of additives in current legislation is that consumers must not be misled. Nevertheless, colourings are sometimes used in a way which creates the impression that a certain type of fruit is present in the food even though that is not the case. Consumer protection must therefore be strengthened in this respect.

Consumer considerations and definitions

It is of no significance to consumer health at all, whether a substance has been used as a processing agent or additive. The decisive factor is whether it remains in the final product or not. Traditionally, however, there have been differences of opinion over what constitutes a processing aid or an additive. For that reason, a long transitional period is required before what is currently defined as a processing aid but which remains in the final product will need to be approved in accordance with this Regulation.

Nanotechnology

Little is currently known about the health risks of nanotechnology. It is not certain that the limit value for the traditional use of an additive and the limit value for nanoparticles of an additive should be the same. It is therefore proposed that the use of nanoparticles should be regulated separately in the Community list.

The new comitology procedure

In the light of the new comitology procedure, a number of amendments are proposed to the Commission's proposals.

OPINION OF THE COMMITTEE ON LEGAL AFFAIRS ON THE LEGAL BASIS

22.3.2007

Mr Miroslav Ouzký
Chairman
Committee on the Environment, Public Health and Food Safety
BRUSSELS

Subject: Opinion on the legal basis of the Proposal for a Regulation of the European Parliament and of the Council on food additives (COM(2006)0428 – C6-0260/2006 – 2006/0145(COD))[1]

Dear Mr Chairman,

By letter of 28 February 2007 you asked the Committee on Legal Affairs pursuant to Rule 35(2), to consider whether the legal basis of the above Commission proposal was valid and appropriate.

The committee considered the above question at its meeting of 20 March 2007.

The lead committee's rapporteur, Ms Westlund, is proposing to change the legal basis of the proposal from Article 95 to Article 95 together with Article 175 of the EC Treaty.

Legal basis

All Community acts must be founded upon a legal basis laid down in the Treaty (or in another legal act which they are intended to implement). The legal basis defines the Community's competence *ratione materiae* and specifies how that competence is to be exercised, namely the legislative instrument(s) which may be used and the decision-making procedure.

In view of the consequences of the legal basis, its choice is of basic importance, particularly for Parliament, since it determines what say, if any, Parliament has in the legislative process.

According to the Court of Justice the choice of legal basis is not a subjective one, but "must be based on objective factors which are amenable to judicial review"[2], such as the aim and

[1] Not yet published in OJ.
[2] Case 45/86 *Commission* v. *Council* [1987] ECR 1439, para. 5.

content of the measure in question[1]. Furthermore, the decisive factor should be the main object of a measure.[2]

According to the case-law of the Court of Justice, a general Treaty article constitutes a sufficient legal basis even though the measure in question also seeks, in a subordinate manner, to attain an aim sought by a specific Treaty article[3].

However, if the view were to be taken that the aims of protecting human health and the establishment and functioning of the internal market are indissolubly linked with each other without one being secondary and indirect in respect of the others, it might be considered that the two legal bases would have to be used, given that the same decision-making procedure (codecision) is provided for in both Articles 95 and 175(1)[4].

The lead committee proposes that Article 175[5] together with Article 95[6] of the EC Treaty

---

[1] Case C-300/89 *Commission* v. *Council* [1991] ECR I-287, para. 10.
[2] Case C-377/98 *Netherlands* v. *European Parliament and Council* [2001] ECR I-7079, para. 27.
[3] Case C-377/98 *Netherlands* v. *European Parliament and Council* [2001] ECR I-7079, paras 27-28; Case C-491/01 *British American Tobacco (Investments) and Imperial Tobacco* [2002] ECR I-11453, paras 93-94.
[4] Case C-165/87 *Commission* v. *Council* [1988] ECR 5545, para. 11.
[5] *Article 175(1)*
1. The Council, acting in accordance with the procedure referred to in Article 251 and after consulting the Economic and Social Committee and the Committee of the Regions, shall decide what action is to be taken by the Community in order to achieve the objectives referred to in Article 174.
[6] *Article 95*
1. By way of derogation from Article 94 and save where otherwise provided in this Treaty, the following provisions shall apply for the achievement of the objectives set out in Article 14. The Council shall, acting in accordance with the procedure referred to in Article 251 and after consulting the Economic and Social Committee, adopt the measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market.
2. Paragraph 1 shall not apply to fiscal provisions, to those relating to the free movement of persons nor to those relating to the rights and interests of employed persons.
3. The Commission, in its proposals envisaged in paragraph 1 concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection, taking account in particular of any new development based on scientific facts. Within their respective powers, the European Parliament and the Council will also seek to achieve this objective.
4. If, after the adoption by the Council or by the Commission of a harmonisation measure, a Member State deems it necessary to maintain national provisions on grounds of major needs referred to in Article 30, or relating to the protection of the environment or the working environment, it shall notify the Commission of these provisions as well as the grounds for maintaining them.
5. Moreover, without prejudice to paragraph 4, if, after the adoption by the Council or by the Commission of a harmonisation measure, a Member State deems it necessary to introduce national provisions based on new scientific evidence relating to the protection of the environment or the working environment on grounds of a problem specific to that Member State arising after the adoption of the harmonisation measure, it shall notify the Commission of the envisaged provisions as well as the grounds for introducing them.
6. The Commission shall, within six months of the notifications as referred to in paragraphs 4 and 5, approve or reject the national provisions involved after having verified whether or not they are a means of arbitrary discrimination or a disguised restriction on trade between Member States and whether or not they shall constitute an obstacle to the functioning of the internal market.
In the absence of a decision by the Commission within this period the national provisions referred to in paragraphs 4 and 5 shall be deemed to have been approved.
When justified by the complexity of the matter and in the absence of danger for human health, the

should be used as the legal basis for the proposal for a regulation. Article 175(1) refers to the objectives of Article 174[1], in particular
— preserving, protecting and improving the quality of the environment,
— protecting human health,
— prudent and rational utilisation of natural resources,
— promoting measures at international level to deal with regional or worldwide environmental problems.

The aim and content of the proposal for Regulation and appraisal of its legal basis

Article 1 of the proposed regulation provides as follows "This Regulation lays down rules on food additives used in foods to ensure the effective functioning of the internal market and a high level of human health protection and consumer protection.

For those purposes, this Regulation provides for:

(a) Community lists of approved food additives;

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

(c) rules on labelling of food additives sold as such."

Recitals 1 to 21 read as follows:

(1) The free movement of safe and wholesome food is an essential aspect of the internal market and contributes significantly to the health and well-being of citizens, and to their social and economic interests.

(2) A high level of protection of human life and health should be assured in the pursuit of Community policies. This Regulation replaces previous Directives and Decisions

---

Commission may notify the Member State concerned that the period referred to in this paragraph may be extended for a further period of up to six months.
7. When, pursuant to paragraph 6, a Member State is authorised to maintain or introduce national provisions derogating from a harmonisation measure, the Commission shall immediately examine whether to propose an adaptation to that measure
8. When a Member State raises a specific problem on public health in a field which has been the subject of prior harmonisation measures, it shall bring it to the attention of the Commission which shall immediately examine whether to propose appropriate measures to the Council.
9. By way of derogation from the procedure laid down in Articles 226 and 227, the Commission and any Member State may bring the matter directly before the Court of Justice if it considers that another Member State is making improper use of the powers provided for in this Article.
10. The harmonisation measures referred to above shall, in appropriate cases, include a safeguard clause authorising the Member States to take, for one or more of the non-economic reasons referred to in Article 30, provisional measures subject to a Community control procedure.

[1] *Article 174(1)*
1. Community policy on the environment shall contribute to pursuit of the following objectives:
— preserving, protecting and improving the quality of the environment,
— protecting human health,
— prudent and rational utilisation of natural resources,
— promoting measures at international level to deal with regional or worldwide environmental problems.

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 harmonises the use of food additives in foods in the Community. This includes the use of food additives in foods covered by Council Directive 89/398/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses and the use of certain food colours for the health marking of meat and the decoration and stamping of eggs. It also harmonises the use of food additives in food additives and food enzymes thus ensuring their safety and quality and facilitating their storage and use. The last category has not previously been regulated at Community level.

(4) Food additives are substances that are not normally consumed as food itself but are added to food intentionally for a technological purpose, such as the preservation of food. However, substances should not be considered as food additives when they are used for the purpose of imparting flavour and/or taste. Moreover, substances considered as foods which may be used for a technological function, such as sodium chloride or saffron for colouring and food enzymes should also not fall within the scope of this Regulation. Finally, as regard food enzymes, they are covered by Regulation (No) …[on food enzymes], which excludes the application of this Regulation.

(5) Substances not consumed as food itself but used intentionally in the processing of foods, which only remain as residues in the final food and do not have a technological effect in the final product (processing aids), should not be covered by this Regulation.

(6) 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 use must not mislead the consumer and their use must bring a benefit to the consumer.

(7) 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) Some food additives are permitted for specific uses for certain authorised oenological practices and processes. The use of such food additives should comply with this Regulation and with the specific provisions laid down in the relevant Community legislation.

(9) In order to ensure uniformity, the risk assessment and approval of food additives should be carried out in accordance with the procedure laid down in Regulation (EC) No […] establishing a common authorisation procedure for food additives, food enzymes and food flavourings.

(10) Under Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety the European Food Safety Authority ('the Authority'), is to be consulted on matters likely to affect public health.

(11) 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 already approved under this Regulation which is prepared by production methods or starting materials significantly different from those included in the risk assessment of the Authority, or different than those covered by the specifications laid down, should be submitted for evaluation by the Authority for an evaluation with emphasis on the specifications. Significantly different production methods or starting materials could mean a change of the production method from extraction from a plant to production by fermentation using a micro-organism or a genetic modification of the original micro-organism.

(13) Food additives should be kept under continuous observation and must be re-evaluated whenever necessary in the light of changing conditions of use and new scientific information.

(14) Member States which have maintained prohibitions on the use of certain additives in certain specific foods which are considered traditional and are produced on their territory should be permitted to continue to apply those prohibitions. Moreover, as regard products such as 'Feta' or 'Salame cacciatore', the present Regulation is without prejudice to more restrictive rules linked to the use of certain denominations under Council Regulation (EEC) No 2081/92 of 14 July 1992 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs and Council Regulation (EEC) No 2082/92 of 14 July 1992 on certificates for specific character for agricultural products and foodstuffs.

(15) Food additives remain subject to the general labelling obligations as provided for in Directive 2000/13/EC and, as the case may be, in Regulations (EC) Nos 1829/2003 and 1830/2003. In addition, specific provisions on labelling of food additives sold as such to the manufacturer or to the final consumer should be contained in this Regulation.

(16) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission.

(17) In order to develop and update Community legislation on food additives in a proportionate and effective way, it is necessary to collect data, share information and coordinate work between Member States. For that purpose, it may be useful to undertake studies to address specific issues with the view to facilitating the decision-making process. It is appropriate that the Community may finance such studies as part of its budgetary procedure. The financing of such measures is covered by Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules and consequently the legal basis for the financing of the above measures will be Regulation (EC) No 882/2004.

(18) Member States are to carry out official controls in order to enforce compliance with this Regulation in accordance with Regulation (EC) No 882/2004.

(19) (...).

(20) Following the adoption of this Regulation the Commission assisted by the Standing Committee on Food Chain and Animal Health should review all the existing authorisations for criteria, other than safety, such as intake, technological need and the potential to mislead the consumer. All food additives that are to continue to be authorised in the Community should 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].

(21) Without prejudice to the outcome of that review, within one year following the adoption of this Regulation, the Commission should set up an evaluation programme for the Authority to re-evaluate the safety of the food additives that were already approved in the Community. That programme should define the needs and the order of priorities according to which the approved food additives are to be examined.

The Commission summarises the content of the proposed regulation follows:

Creation of a Regulation of the European Parliament and of the Council on food additives that lays down the principles for the use of food additives and lays down the positive list of substances that may be used as food additives.

Repeal of Council Directive 89/107/EEC on the approximation of the laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption, European Parliament and Council Directives 94/35/EC on sweeteners for use in foodstuffs, 94/36/EC on colours for use in foodstuffs and 95/2/EC on food additives other than colours and sweeteners and the European Parliament and the Council Decision No.

292/97/EC on the maintenance of national laws prohibiting the use of certain additives in the production of certain specific foodstuffs.

It is noted that the Commission's explanatory memorandum provides no justification for recourse to Article 95 alone as legal basis.

Appraisal

In view of the provisions of the proposal for a regulation and in particular the recitals set out *in extenso* above, it is considered that that the aims of protecting human health and the establishment and functioning of the internal market are indissolubly linked with each other without one being secondary and indirect in respect of the other. The proposal's aims connected with the protection of human health and the functioning of the internal market seem equally balanced. It is therefore considered that the legal basis should be both Article 95 and Article 175 of the EC Treaty.

Conclusion

At its meeting of 20 March 2007 the Committee on Legal Affairs accordingly decided, unanimously[1], to recommend that the legal basis of the proposal for a Regulation of the European Parliament and of the Council on food additives should be Article 95 and Article 175 of the EC Treaty.

Yours sincerely,

Giuseppe Gargani

[1] The following were present for the final vote: Giuseppe Gargani (chairman), Cristian Dumitrescu (vice-chairman), Rainer Wieland (vice-chairman), Francesco Enrico Speroni (vice-chairman), Sharon Bowles, Mogens N.J. Camre, Marek Aleksander Czarnecki, Monica Frassoni, Jean-Paul Gauzès, Kurt Lechner, Klaus-Heiner Lehne, Katalin Lévai, Eva Lichtenberger, Toine Manders, Antonio Masip Hidalgo, Hans-Peter Mayer, Manuel Medina Ortega, Marie Panayotopoulos-Cassiotou, Michel Rocard, Aloyzas Sakalas, Gabriele Stauner, József Szájer, Jacques Toubon, Jaroslav Zvěřina, Tadeusz Zwiefka.

PROCEDURE

Title	Food additives
References	COM(2006)0428 - C6-0260/2006 - 2006/0145(COD)
Date submitted to Parliament	28.7.2006
Committee responsible Date announced in plenary	ENVI 5.9.2006
Committee(s) asked for opinion(s) Date announced in plenary	ITRE IMCO AGRI 5.9.2006 5.9.2006 5.9.2006
Not delivering opinions Date of decision	ITRE IMCO AGRI 4.10.2006 13.9.2006 11.9.2006
Rapporteur(s) Date appointed	Åsa Westlund 14.9.2006
Legal basis disputed Date of JURI opinion	JURI 20.3.2007
Discussed in committee	26.2.2007
Date adopted	11.4.2007
Result of final vote	+: 55 –: 0 0: 0
Members present for the final vote	Adamos Adamou, Georgs Andrejevs, Margrete Auken, Liam Aylward, Pilar Ayuso, Johannes Blokland, John Bowis, Frieda Brepoels, Hiltrud Breyer, Dorette Corbey, Chris Davies, Avril Doyle, Mojca Drčar Murko, Anne Ferreira, Karl-Heinz Florenz, Françoise Grossetête, Cristina Gutiérrez-Cortines, Satu Hassi, Gyula Hegyi, Dan Jørgensen, Christa Klaß, Holger Krahmer, Aldis Kušķis, Peter Liese, Linda McAvan, Alexandru-Ioan Morţun, Roberto Musacchio, Riitta Myller, Péter Olajos, Miroslav Ouzký, Antonyia Parvanova, Vittorio Prodi, Frédérique Ries, Dagmar Roth-Behrendt, Guido Sacconi, Karin Scheele, Horst Schnellhardt, Kathy Sinnott, Antonios Trakatellis, Anja Weisgerber, Åsa Westlund, Glenis Willmott
Substitute(s) present for the final vote	Giovanni Berlinguer, Jens-Peter Bonde, Iles Braghetto, Philip Bushill-Matthews, Antonio De Blasio, Christofer Fjellner, Rebecca Harms, Karin Jöns, Kartika Tamara Liotard, Jiří Maštálka, Miroslav Mikolášik, Stefan Sofianski, Andres Tarand, Lambert van Nistelrooij
Substitute(s) under Rule 178(2) present for the final vote	Gabriela Creţu