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***I
REPORT

on the proposal for a regulation of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings
(COM(2006)0423 – C6-0258/2006 – 2006/0143(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.

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on the proposal for a regulation of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings
(COM(2006)0423 – C6-0258/2006 – 2006/0143(COD))

(Codecision procedure: first reading)

The European Parliament,

– having regard to the Commission proposal to the European Parliament and the Council (COM(2006)0423)[1],

– having regard to Article 251(2) and Article 95 of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C6-0258/2006),

– 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 (A6-0153/2007),

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 2
(2) A high level of protection of human life and health ***should*** be assured in the pursuit of Community policies.	(2) A high level of protection of human life and health ***and of the environment needs to*** be assured in the pursuit of Community policies.

[1] Not yet published in OJ.

Amendment 2
Recital 4

(4) Regulation (EC) No XXX/2006 of the European Parliament and of the Council of … on food additives, Regulation (EC) No YYY/2006 of the European Parliament and of the Council of … on food enzymes and Regulation (EC) No ZZZ/2006 of the European Parliament and of the Council of … on food flavourings and certain food ingredients with flavouring properties lay down ***harmonised*** criteria and requirements concerning the assessment and authorisation of these substances.	(4) Regulation (EC) No XXX/2006 of the European Parliament and of the Council of … on food additives, Regulation (EC) No YYY/2006 of the European Parliament and of the Council of … on food enzymes and Regulation (EC) No ZZZ/2006 of the European Parliament and of the Council of … on food flavourings and certain food ingredients with flavouring properties lay down criteria and requirements concerning the assessment and authorisation of these substances.

Justification

It is not certain that the criteria should be exactly the same for the various substances. One reason why they are dealt with in three different regulations is that there are, nevertheless, various differences to take into account.

Amendment 3
Recital 5 a (new)

	(5a) Transparency in the production and handling of food is absolutely crucial to achieving consumer credibility.

Justification

Transparency is a crucial factor if consumers are to have confidence in the EU's way of managing food-related issues.

Amendment 4
Recital 7 a (new)

	(7a) The criteria laid down for authorisation in Regulations (EC) No XXX/2006, (EC) No YYY/2006 and (EC) No ZZZ/2006 should also be fulfilled for authorisation pursuant to this Regulation.

Justification

This is self-evident but is not set out specifically in the Commission's proposal.

Amendment 5
Recital 9

(9) In accordance with the framework for risk assessment in matters of food safety established by 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 placing of substances on the market must be authorised only after ***a*** scientific assessment, of the highest possible standard, of the risks that they pose to human health. This assessment, which must be carried out under the responsibility of the European Food Safety Authority (hereinafter referred to as "the Authority"), must be followed by a risk management decision taken by the Commission under a regulatory procedure that ensures close cooperation between the Commission and the Member States.	(9) In accordance with the framework for risk assessment in matters of food safety established by 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 placing of substances on the market must be authorised only after ***an independent*** scientific assessment, of the highest possible standard, of the risks that they pose to human health. This assessment, which must be carried out under the responsibility of the European Food Safety Authority (hereinafter referred to as "the Authority"), must be followed by a risk management decision taken by the Commission under a regulatory procedure that ensures close cooperation between the Commission and the Member States.

Amendment 6
Recital 10

(10) It is recognised that***, in some cases,*** scientific risk assessment alone cannot provide all the information on which a risk management decision should be based, and that other legitimate factors relevant to the matter under consideration ***may*** be taken into account.	(10) It is recognised that scientific risk assessment alone cannot provide all the information on which a risk management decision should be based, and that other legitimate factors relevant to the matter under consideration ***must*** be taken into account.

Justification

Other legitimate factors relevant to the matter - safety concerns related to the health of the consumer, reasonable technological need, and benefits and advantages for the consumer - must be considered in all cases.

Amendment 7
Recital 11

(11) So that both business operators in the sectors concerned and the public are kept	(11) So that both business operators in the sectors concerned and the public are kept

informed of the authorisations in force, the authorised substances ***should*** be included on a Community list created, maintained and published by the Commission.	informed of the authorisations in force, the authorised substances ***need to*** be included on a Community list created, maintained and published by the Commission.

Justification

Consumers and the industry must be able to assume that substances and uses which are not included on the Community list are unauthorised.

Amendment 8
Recital 13

(13) The common authorisation procedure for the substances must fulfil transparency and public information requirements while guaranteeing applicants' right to preserve the confidentiality of certain information.	(13) The common authorisation procedure for the substances must fulfil transparency and public information requirements while guaranteeing applicants' right to preserve the confidentiality of certain information***, in duly justified cases and for stated reasons.***

Amendment 9
Recital 16

(16) In the interests of efficiency and legislative simplification, there should be a medium-term examination as to whether to extend the scope of the common procedure to other legislation in the area of food.	(16) In the interests of efficiency and legislative simplification, there should be a medium-term examination***, including consultation of all stakeholders***, as to whether to extend the scope of the common procedure to other legislation in the area of food.

Amendment 10
Recital 18

(18) 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[9],	(18) 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[9]. ***The Commission should, as appropriate, consult stakeholders in preparing the measures to put before the Committee referred to in the above Decision,***
[9] OJ L 184, 17.7.1999, p. 23.	[9] OJ L 184, 17.7.1999, p. 23. ***Decision as amended by Decision 2006/512/EC (OJ L 200, 22.7.2006, p. 11).***

Justification

Specific provisions to allow for the informal consultation of stakeholders to take place prior to any Decision in the SCoFCAH should be included to ensure maximum transparency and openness.

Amendment 11
Article 1, paragraph 1

1. This Regulation lays down a common assessment and authorisation procedure (hereinafter referred to as the "common procedure") for food additives, food enzymes, food flavourings and sources of food flavourings used or intended for use in or on foodstuffs (hereinafter referred to as the "substances"), which contributes to the free movement of ***these substances*** within the Community.	1. This Regulation lays down a common assessment and authorisation procedure (hereinafter referred to as the "common procedure") for food additives, food enzymes, food flavourings and sources of food flavourings used or intended for use in or on foodstuffs (hereinafter referred to as the "substances"), which contributes to ***improved consumer protection and public health and*** the free movement of ***food*** within the Community.

Justification

The primary aim of this legislation is to contribute to the free movement of food within the Community.

Amendment 12
Article 1, paragraph 1, subparagraph 1 a (new)

This Regulation shall not apply to products permitted under Regulation (EC) No 2065/2003 of the European Parliament and of the Council of 10 November 2003 on smoke flavourings used or intended for use in or on foods[1].

[1]OJ L 309, 26.11.2003, p. 1.

Justification

Smoke flavourings are adequately and appropriately governed by Regulation (EC) No 2065/2003. Explicitly exempting them from this regulation will make for clearer legislation.

Amendment 13
Article 2, paragraph 1

1. Under each sectoral food law, substances that have been authorised to be placed on the Community market shall be included on a list the content of which is determined by the said law (hereinafter referred to as the "Community list"). The Community list shall be updated by ***the Commission***. It shall be published in the Official Journal of the European Union.	1. Under each sectoral food law, substances that have been authorised to be placed on the Community market shall be included on a list the content of which is determined by the said law (hereinafter referred to as the "Community list"). The Community list shall be updated by ***a regulation of the European Parliament and of the Council.*** It shall be published in the Official Journal of the European Union.

Justification

Most modifications and updates of the community list have been subject to controversial debates both in the European Parliament and in Council. Although often first reading agreements could be achieved, the decision should not be left to the Commission and its comitology procedure.

Amendment 14
Article 2, paragraph 1, subparagraph 1 a (new)

Substances included on the Community list may be used by all food business operators subject to the conditions applicable to them, provided their use is not restricted under Article 12(6a).

Justification

The inclusion of a substance on Community lists requires extensive toxicological studies. It is understandable that responsible manufacturers who carry out these studies, making a large financial commitment in the process, are keen to benefit, at least for a certain amount of time, from the advantages associated with authorisation (see Amendment 60 by Horst Schnellhardt).

Amendment 15
Article 3, paragraph 2, subparagraph 2

However, for the updates referred to in Article 2(2)(b) and (c), the Commission shall seek the opinion of the Authority only if these updates are liable to have an effect on ***public*** health.	However, for the updates referred to in Article 2(2)(b) and (c), the Commission shall seek the opinion of the Authority only if these updates are liable to have an effect on ***human*** health.

Amendment 16
Article 3, paragraph 3

3. The common procedure shall end with the adoption by the ***Commission*** of a regulation implementing the update, ***in accordance with Article 7.***	3. The common procedure shall end with the adoption by the ***European Parliament and the Council*** of a regulation implementing the update.

Justification

The common procedure should be based on co-decision. Modifications and updates of the community list have often been subject to controversial debates both in the European Parliament and in Council, thus it should not be left to the Commission and its comitology procedure.

Amendment 17
Article 3, paragraph 3a (new)

	3a. All authorisations for use of food additives, food enzymes and food flavourings shall be reviewed on a regular basis.

Justification

It is important that the use of substances in food is consistent with the latest scientific research. Moreover, it is important for certain groups of consumers that substances which

are not used are deleted from the list, along with uses which are no longer current.

Amendment 18
Article 3, paragraph 4, subparagraph 1

4. By way of derogation from paragraph 3, the Commission may end the common procedure and decide not to proceed with a planned update, at any stage of the procedure, if it judges that such an update is not justified. Where applicable, it shall take account of the opinion of the Authority, any relevant provisions of Community law and any other legitimate factors relevant to the matter under consideration.	4. By way of derogation from paragraph 3, the Commission may end the common procedure and decide not to proceed with a planned update, at any stage of the procedure ***until a proposal for a regulation has been presented to the European Parliament and the Council***, if it judges that such an update is not justified. Where applicable, it shall take account of the opinion of the Authority, any relevant provisions of Community law and any other legitimate factors relevant to the matter under consideration.

Or. en

Justification

The common procedure should be based on co-decision. Modifications and updates of the community list have often been subject to controversial debates both in the European Parliament and in Council, thus it should not be left to the Commission and its comitology procedure.

Amendment 19
Article 3, paragraph 4, subparagraph 2

In such cases, ***where applicable,*** the Commission shall inform the applicant directly, indicating in its letter the reasons for the update not being considered justified.	In such cases the Commission shall ***make public its decision, subject to the provisions of Article 12, and shall*** inform the applicant directly, indicating in its letter the reasons for the update not being considered justified.

Justification

Decisions not to take decisions must also be made public. Transparency is a crucial factor if consumers are to have confidence in the EU's way of managing food-related issues.

Amendment 20
Article 4, paragraph 1

1. On receipt of an application to update the Community list, the Commission:	1. On receipt of an application to update the Community list, the Commission *shall*:
a) *shall* acknowledge receipt of the application in writing to the applicant within 14 working days of receiving it;	a) acknowledge receipt of the application in writing to the applicant within 14 working days of receiving it;
b) ***where applicable,*** notify the Authority of the application and request its opinion.	b) notify the Authority of the application and request its opinion.
The application shall be made available to the Member States ***by the Commission***.	The application shall be made available ***by the Commission*** to ***the European Parliament,*** the Member States ***and to stakeholders***.

Justification

Most modifications and updates of the community list have been subject to controversial debates both in the European Parliament and in Council. Although often first reading agreements could be achieved, the decision should not be left to the Commission and its comitology procedure.

Amendment 21
Article 4, paragraph 2

2. Where it initiates the procedure on its own initiative, the Commission shall inform the Member States and, where applicable, request the opinion of the Authority.	2. Where it initiates the procedure on its own initiative, the Commission shall inform the Member States ***and make public the fact*** and, where applicable, request the opinion of the Authority.

Justification

Transparency is a crucial factor if consumers are to have confidence in the EU's way of managing food-related issues.

Amendment 22
Article 5, paragraph 1

1. The Authority shall give its opinion within ***six months*** of receipt of a valid application.	1. The Authority shall give its opinion within ***nine months*** of receipt of a valid application.

Justification

Given the resources at the EFSA's disposal and the quality standards required of the EFSA's opinion, the Commission's proposal for such a short period of time is not reasonable.

Amendment 23
Article 5, paragraph 2

2. The Authority shall forward its opinion to the Commission, the Member States and***, where appropriate,*** the applicant.	2. The Authority shall forward its opinion to the Commission, the Member States and the applicant. ***The opinion shall also be made public, subject to the provisions of Article 12.***

Justification

The applicant must ALWAYS be informed and the EFSA's opinion must be made public.

Amendment 24
Article 6, paragraph 1

1. ***In duly justified cases*** where the Authority requests additional information from applicants, the period referred to in Article 5(1) may be extended. After consulting the applicant, the Authority shall lay down a period within which this information can be provided and inform the Commission of the additional period needed. If the Commission does not object within eight working days of being informed by the Authority, the period referred to in Article 5(1) shall be automatically extended by the additional period.	1. Where the Authority requests additional information from applicants, the period referred to in Article 5(1) may be extended. After consulting the applicant, the Authority shall lay down a period within which this information can be provided and inform the Commission of the additional period needed. If the Commission does not object within eight working days of being informed by the Authority, the period referred to in Article 5(1) shall be automatically extended by the additional period.

Justification

If the application does not provide all data needed by the Authority to assess the risk of a given substance, the period available should be extended in order to allow a serious risk assessment.

Amendment 25
Article 6, paragraph 3

3. Where applicants submit additional information on their own initiative, they	3. Where applicants submit additional information on their own initiative, they

shall send it to the Authority and to the Commission. In such cases, the Authority shall give its opinion within the original period.	shall send it to the Authority and to the Commission. In such cases, the Authority shall give its opinion within the original period***, unless there are special reasons for extending the period***.

Justification

There must be no incentives for the applicant to submit additional information once the deadline has expired. Without the above addendum, there would unfortunately be such a negative incentive.

Amendment 26
Article 7

Within ***nine months*** of the Authority giving its opinion, the Commission shall submit to the ***Committee referred to in Article 14(1)*** a ***draft*** regulation updating the Community list, taking account of the opinion of the Authority, any relevant provisions of Community law and any other legitimate factors relevant to the matter under consideration.	Within ***six months*** of the Authority giving its opinion, the Commission shall submit to the ***European Parliament and the Council*** a ***proposal for a*** regulation updating the Community list, taking account of the opinion of the Authority, any relevant provisions of Community law and any other legitimate factors relevant to the matter under consideration.
	The Commission shall justify its proposal and explain the considerations on which it is based.
Where the ***draft*** regulation is not in accordance with the opinion of the Authority, the Commission shall explain the ***difference.***	Where the ***proposal for a*** regulation is not in accordance with the opinion of the Authority, the Commission shall explain the ***reasons for its decision***.
The regulation shall be adopted in accordance with the procedure referred to in Article 14(2).	

Justification

Most modifications and updates of the community list have been subject to controversial debates both in the European Parliament and in Council. Although often first reading agreements could be achieved, the decision should not be left to the Commission and its comitology procedure.

Amendment 27
Article 8, paragraph 1

1. Where the Commission requests additional information from applicants on matters concerning risk management, it shall determine, together with the applicant, a period within which this information can be provided. In such cases, the period referred to in Article 7 ***may be extended accordingly***.	1. Where the Commission requests additional information from applicants on matters concerning risk management, it shall determine, together with the applicant, a period within which this information can be provided. In such cases, ***the Commission may extend*** the period referred to in Article 7 ***and shall inform the Member States of the extension***.

Amendment 28
Article 10

The periods referred to in Article 5(1) and Article 7 may be extended by the Commission on its own initiative or, where applicable, at the Authority's request, if the nature of the matter in question so justifies, without prejudice to Article 6(1) and Article 8(1). In such cases***, where appropriate,*** the Commission shall inform the applicant of the extension and the reasons for it.	The periods referred to in Article 5(1) and Article 7 may be extended by the Commission on its own initiative or, where applicable, at the Authority's request, if the nature of the matter in question so justifies, without prejudice to Article 6(1) and Article 8(1). In such cases the Commission shall inform the applicant ***and the Member States*** of the extension and the reasons for it.

Justification

The applicant should always be informed of any extension of the time limits. Member states should be informed as well.

Amendment 29
Article 11, paragraph 1 a (new)

	The Commission shall ensure the transparency of the authorisation procedure by making public all applications and by making all relevant material in the matter available to the public.

Justification

Transparency is a crucial factor if consumers are to have confidence in the EU's way of handling food-related issues.

Amendment 30
Article 12, paragraph 1, subparagraph 1

1. ***Among the*** information provided by applicants, confidential treatment ***may be given to information*** the disclosure ***of which*** might significantly harm their competitive position.	1. Information provided by applicants ***may be given*** confidential treatment ***only where*** the disclosure ***thereof*** might significantly harm their competitive position.

Justification

Transparency is a crucial factor if consumers are to have confidence in the EU's way of handling food-related issues. There may sometimes be grounds, however, for treating information confidentially.

Amendment 31
Article 12, paragraph 1, subparagraph 2, introductory part

Information relating to the following ***shall not***, in any case, be considered confidential:	Information relating to the following ***may never***, in any case, be considered confidential:

Justification

Transparency is a crucial factor if consumers are to have confidence in the EU's way of handling food-related issues. There may sometimes be grounds, however, for treating information confidentially.

Amendment 32
Article 12, paragraph 3

3. The Commission shall decide which information can remain confidential and notify applicants accordingly.	3. The Commission shall decide which information can remain confidential and notify applicants ***and the Member States*** accordingly.

Justification

Member states should also be informed.

Amendment 33
Article 12, paragraph 6 a (new)

	6a. Scientific data and other information provided by applicants may not be used for the benefit of a subsequent applicant for a

period of five years from the date of authorisation, unless the subsequent applicant has agreed with the prior applicant that such data and information may be used and costs are shared accordingly, where:

(a) the scientific data and other information were designated as proprietary by the prior applicant at the time the prior application was made; and

(b) the prior applicant had exclusive rights of reference to the proprietary data at the time the prior application was made; and

(c) the food additive could not have been authorised without the submission of the proprietary data by the prior applicant.

Justification

The inclusion of a substance on Community lists requires extensive toxicological studies. It is understandable that responsible manufacturers who carry out these studies, making a large financial commitment in the process, are keen to benefit, at least for a certain amount of time, from the advantages associated with authorisation.

Amendment 34
Article 14, 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 due 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.

EXPLANATORY STATEMENT

Environmental considerations
In accordance with the Cardiff process, environmental aspects must be integrated into all EU legislation.

It is particularly relevant in this legislation since 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. Negative environmental effects should therefore be taken into consideration when deciding to grant authorisation or not. Article 175 of the Treaty establishing the European Communities should therefore also form the basis for the regulation.

Transparency

Transparency is a crucial factor if consumers are to feel confident in the EU's way of managing food-related issues. The Commission must, therefore, ensure the transparency of the authorisation procedure by making public all applications and making all relevant material in the matter available to the public. Producers applying for authorisation must always be informed directly on matters concerning their application.

The Commission should be able, without difficulty, to explain the considerations on which its decision is based. A transparent explanation of this nature would benefit consumers, industry and the Member States' authorities. The Commission should, therefore, always make public its proposals for decisions, justify its proposal and explain the considerations on which its decision is based. Decisions not to take decisions must also be made public.

Where the adopted regulation departs from the Commission's original proposal to the Committee on the Food Chain and Animal Health, the Commission shall also explain the background to the final decision.

Food safety
Given the resources at the EFSA's disposal and the quality standards required of the EFSA's opinion, six months, as the Commission has proposed, is not a reasonable period within which to produce an opinion on an application. Having regard to food safety, therefore, it is proposed that this time period be extended so that the EFSA has nine months in which to present an opinion.

It is important that the use of substances in food is consistent with the latest scientific research. It is also important for certain groups of consumers that substances and uses which are no longer current are removed from the list. All authorisations for use of food additives, food enzymes and food flavourings must therefore be reviewed on a regular basis.

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

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 for a regulation on establishing a common authorisation procedure for food additives, food enzymes and food flavourings (COM(2006)0423) – C6-0258/2006 – 2006/0143(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 content of the measure in question[3]. Furthermore, the decisive factor should be the main object of a measure.[4]

[1] Not yet published in OJ.
[2] Case 45/86 *Commission* v. *Council* [1987] ECR 1439, para. 5.
[3] Case C-300/89 *Commission* v. *Council* [1991] ECR I-287, para. 10.
[4] Case C-377/98 *Netherlands* v. *European Parliament and Council* [2001] ECR I-7079, para. 27.

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[1].

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)[2].

The lead committee proposes that Article 175[3] together with Article 95[4] of the EC Treaty

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[1] 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.

[2] Case C-165/87 *Commission* v. *Council* [1988] ECR 5545, para. 11.

[3] *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.

[4] *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 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

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 provides as follows:

"1. This Regulation lays down a common assessment and authorisation procedure (hereinafter referred to as the 'common procedure') for food additives, food enzymes, food flavourings and sources of food flavourings used or intended for use in or on foodstuffs (hereinafter referred to as the 'substances'), which contributes to the free movement of these substances within the Community.

2. The common procedure shall set the procedural arrangements for updating the lists of substances the marketing of which is authorised in the Community pursuant to Regulation (EC) No XXX/2006, Regulation (EC) No YYY/2006 and Regulation (EC) No ZZZ/2006 (hereinafter referred to as the 'sectoral food laws').

3. The criteria according to which substances can be included on the Community list provided for in Article 2, the content of the Regulation referred to in Article 7 and, where applicable, the transitional provisions concerning ongoing procedures are laid down in each sectoral food law."

Recitals 1, 2 and 3 read as follows:

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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.

"(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.

(3) So as to protect human health, the safety of additives, enzymes and flavourings for use in foodstuffs for human consumption must be assessed before they are placed on the Community market."

The content of the proposal for a regulation may be summarised as follows:

Chapter I: General principles

A common procedure is established for assessing and authorising additives, enzymes and flavourings. This procedure has been designed to be simple, fast and effective, while respecting the principles of good administration and legal certainty. It is centred around the updating, on the basis of the criteria laid down in the sectoral laws, of a list of authorised substances that must be created and maintained by the Commission.

Chapter II: Common procedure

Under the proposed procedure, requests for updates must be addressed to the Commission, without first going through a national authority.

The Commission has to send the request file to the Authority and to the Member States and to seek the opinion of the Authority, which must issue such opinion within six months.
So as to ensure the binding effect of the updating measures, the proposal provides for their adoption to take the legal form of a regulation adopted in accordance with the comitology procedure.

When the list is being updated within the framework of this proposal for a Regulation, any other relevant legitimate factors must be taken into account. Thus, when initiating the decision-making process, the Commission, as risk manager, may propose a measure that is not in line with the outcome of the risk assessment carried out under the responsibility of the Authority. In such cases, the Commission must explain its reasons for such a departure. This is in line with the Codex Alimentarius General Principles on Risk Analysis.

Chapter III: Miscellaneous provisions

So as to take account of the specific characteristics of each sectoral food law, this proposal gives the Commission the power, following consultation of the Authority, to take decisions on various details of the procedure and provides for a certain degree of flexibility as regards complex and sensitive cases.

All non-confidential data should be made available to the public.

If the Member States or the Commission consider that a substance that has been authorised in accordance with this proposal poses serious risks to human health, animal health or the

environment, emergency measures must be adopted.

According to the explanatory memorandum "As part of the efforts undertaken to improve Community legislation on the basis of the 'farm to table' concept, in the White Paper on Food Safety, the Commission announced its intention to update and complete existing legislation with regard to additives and flavourings and to lay down specific provisions in respect of enzymes. (Actions 11 and 13 of the White Paper).

This proposal aims to ensure the proper functioning of the internal market, while also ensuring a high level of protection of human life and health as regards food additives, food enzymes and food flavourings.

In order to do this, it aims to establish a common authorisation procedure that is centralised, effective, expedient and transparent and that is based on risk assessment carried out by the European Food Safety Authority (hereinafter referred to as 'the Authority') and risk management system in which the Commission and the Member States take action within the framework of a regulatory committee procedure. It assigns to the Commission, on the basis of the Authority's scientific assessments, the task of creating, maintaining and updating a general positive list for each category of substances concerned. The inclusion of a substance on one of these lists means that its use is authorised in general for all operators on the Community market."

The Commission justifies recourse to Article 95 as follows: "This proposal aims to improve the conditions for the functioning of the internal market, since it will be possible for products authorised in accordance with the proposed procedure to be used throughout the Community. The Regulation envisaged will lead to the Member States' legal provisions concerning the use of food additives, food enzymes and food flavourings being harmonised in the form of a positive list of authorised substances to be created by the Commission pursuant to the Regulation."

Appraisal

On the basis of this analysis of the aim and content of the proposal for a regulation, it is considered 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 evidently has both aims connected with the protection of human health, and aims designed to improve the functioning of the internal market.

It is therefore considered that the legal basis should be 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 you that the legal basis of the proposal for a Regulation of the

[1] The following were present for the final vote: Giuseppe Gargani (chairman), Cristian Dumitrescu (vice-

European Parliament and of the Council for a regulation on establishing a common authorisation procedure for food additives, food enzymes and food flavourings should be Article 95 and Article 175 of the EC Treaty.

Yours sincerely,

(sign.) Giuseppe Gargani

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	Common authorisation procedure for food additives, food enzymes and food flavourings
References	COM(2006)0423 - C6-0258/2006 - 2006/0143(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	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, Jens Holm, 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, 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	Alfonso Andria, Giovanni Berlinguer, Jens-Peter Bonde, Iles Braghetto, Philip Bushill-Matthews, Christofer Fjellner, Rebecca Harms, Karin Jöns, Kartika Tamara Liotard, Jiří Maštálka, Miroslav Mikolášik, Andres Tarand, Lambert van Nistelrooij
Substitute(s) under Rule 178(2) present for the final vote	Gabriela Creţu