COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 24.10.2007
COM(2007) 672 final

2006/0143 (COD)

Amended 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

(presented by the Commission pursuant to Article 250 (2) of the EC Treaty)

EXPLANATORY MEMORANDUM

1. PROCEDURE

1. On 28th July 2006, the Commission adopted the proposal for a European Parliament and Council Regulation establishing a common authorisation procedure for food additives, food enzymes and food flavourings [Document (COM (2006)0423 final)] as part of a package of four proposals on food improvement agents. The proposal was submitted to the Council and the European Parliament on 28th July 2006.

2. The Economic and Social Committee adopted its opinion on 25th April 2007.

3. The Council has agreed a 'general approach' on the proposal at the EPSCO meeting on 31st May 2007.

4. The European Parliament has given in first reading a favourable opinion on the proposal on 10th July 2007.

5. The present proposal amends the original proposal [COM (2006)0423 – 2006/0143(COD)] so as to take into account the amendments of the European Parliament that were accepted by the Commission.

With regard to the original proposal, the European Parliament adopted 31 amendments. Commissioner Kyprianou had indicated to the plenary meeting on 9th July 2007 that the Commission could accept most of the amendments, wholly or in part, and subject to rewording. From the adopted amendments the Commission cannot accept the following amendments: 14, 20, 31, and 33.

The amendments in the revised proposal are in **bold and underlined**. A number of amendments have been reformulated so as to ensure consistency of the terminology used throughout the proposal.

Within certain Articles, the numbering of the paragraphs has been adapted in order to take into account the addition or deletion of elements in the Commission proposal.

II. OBJECTIVES OF THE PROPOSAL

6. 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 food 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 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 (EFSA) and a risk management system in which the Commission takes action within the framework of a regulatory committee procedure (comitology). It assigns to the Commission, on the basis of the EFSA'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 in the Community.

7. The proposed Regulation on the common authorisation procedure is part of the package of proposals on 'food improvement agents' which refers to the proposals on food additives, food enzymes and flavourings. It contributes to the Commission's simplification programme and also provides for harmonisation and promotes consistency between the three related areas.

III. OVERVIEW OF THE AMENDMENTS OF THE EUROPEAN PARLIAMENT

8. Technical/editorial amendments

The majority of the proposed amendments aim to improve the proposal from a technical and editorial point of view. These amendments have largely been taken over by the Commission in some cases subject to editorial changes (Amendments concerned: 1, 2, 3, 4, 5, 6, 8, 9, 10, 11, 12, 15, 19, 21, 23, 24, 25, 27, 28, 30, 32).

Amendment 23 is acceptable in substance. However, it is already stated in Article 11 that the Authority shall make its opinions public without delay; therefore repetition of the same provision in Article 5(2) is not appropriate for reasons of legal drafting.

Amendment 31, although editorial, cannot be accepted for reasons of legal drafting.

9. Transparency

Amendments 9, 10, 19, 21, 27, 28 and 32 strengthen the transparency and information provisions which were already underlying principles of the Commission proposal.

However, amendment 20 requires all application files to become available to stakeholders. The Commission intends to make public a list of all requests for authorisation and information on progress, but routine publication of the full application files is not acceptable. Access to documents held by the Commission can be granted under the provisions of Regulation (EC) No 1049/2001 of the European Parliament and of the Council regarding public access to European Parliament, Council and Commission documents.

10. 5 year data protection with individual authorisations (Article 2 and Article 12)

The proposal provides for a system of positive lists of food additives, food enzymes and flavourings. The inclusion of a substance on one of these lists means that its use is authorised in general for all operators in the Community. This is the situation today with regard to food additives.

Amendments 14 and 33 provide for a 5-year period of data protection and as a result preferential authorisation of the substance during this time for the company that provided the data. Such provision would change radically the present system for food additives which has been in place for a long time and is generally adopted internationally. It would also result in a duplication of regulatory approaches (individual authorization for 5 years followed by a general authorisation), a complication of systems of control and increased administrative procedures. This approach is thus not in line with the objective of the simplification of the regulatory framework. Finally a system that grants exclusive rights to individual operators could hinder the free movement of products that are safe and comply with the criteria of the specific legislation, which goes against the objectives of a measure made under Article 95 of the EC Treaty. Therefore, these amendments have not been taken over in the amended proposal.

11. Deadlines (Article 5 (1) and Article 7(1))

Amendment 22 increases the time for the European Food Safety Authority (Authority) to give its opinion from six to nine months. This is accepted in the amended proposal.

On the other hand amendment 37 reduces the time for the Commission to present a draft measure to the Standing Committee from nine to six months. There are cases, notably for food additives, where six months will not be enough for the Commission to present a measure after having consulted the Member States and relevant stakeholders on the technological need, benefit to the consumer, the potential to mislead the consumer and other relevant factors. This form of consultation taking into account the views of stakeholders when drafting proposals can only be achieved if adequate time is available. Therefore this part of amendment 37 is not integrated in the amended proposal.

12. Comitology (Article 7 and Article 14)

The Commission proposal referred to the normal regulatory procedure since it was adopted around the time that Council Decision 2006/512/EC, amending Decision 1999/468/EC laying down the procedures for the exercise of implementing powers conferred on the Commission, was adopted. Therefore the proposal should be amended to take the new regulatory procedure with scrutiny into account.

Amendments 34, 35, 36 and 37 support comitology for updating the lists of food additives, food enzymes and flavourings whilst they align the text of the proposal to the provisions of the new regulatory procedure with scrutiny. These amendments are welcomed and accepted in principle, subject to some editorial changes. Amendment 36 in particular, although accepted in principle, is not taken on board in the text of Article 2(1) as it is already covered by the amendment introduced in Article 7. In addition the possibility to use the urgency procedure is introduced for the removal of substances from the Community list and for adding, removing or changing specifications or restrictions of use, in case of a particular risk to human health.

13. Pursuant to Article 250(2) of the EC-Treaty, the Commission amends it proposals in accordance with the lines set out above.

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(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission[1],

Having regard to the opinion of the European Economic and Social Committee[2],

Acting in accordance with the procedure laid down in Article 251 of the Treaty

Whereas:

(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 **and of the environment** 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.

(4) Regulation (EC) No XXX/2006 of the European Parliament and of the Council of … on food additives[3], Regulation (EC) No YYY/2006 of the European Parliament and of the Council of … on food enzymes[4] 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[5] lay down ~~harmonised~~ criteria and requirements concerning the assessment and authorisation of these substances.

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1 OJ C […], […], p. […].
2 OJ C **168, 20.7.2007, p 34.**
3 OJ L […], […], p. […].
4 OJ L […], […], p. […].
5 OJ L […], […], p. […].

(5) It is envisaged, in particular, that food additives, food enzymes and food flavourings, to the extent that the safety of the latter must be assessed in accordance with Regulation (EC) No ZZZ/2006, must not be placed on the market or used in foodstuffs for human consumption, in accordance with the conditions laid down in each sectoral food law, unless they are included on the Community list.

(6) Transparency in the production and handling of food is absolutely crucial to achieving consumer confidence.

(7) In this context, it appears appropriate to establish a common Community assessment and authorisation procedure for these three categories of substances that is effective, time-limited and transparent, so as to contribute to their free movement within the Community market.

(8) This common procedure must be founded on the principles of good administration and legal certainty and must be implemented in compliance with these principles.

(9) This Regulation will thus complete the regulatory framework concerning the authorisation of the substances by laying down the various stages of the procedure, the deadlines for these stages, the role of the parties involved and the principles that apply. Nevertheless, for some aspects of the procedure, it is necessary to take the specific characteristics of each sectoral food law into consideration.

(10) 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[6], 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.

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

(12) 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~~ **must** be taken into account.

(13) 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.

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[6] OJ L 31, 1.2.2002, p. 1. Regulation as amended by Regulation (EC) No 1642/2003 (OJ L 245, 29.9.2003, p. 4).

(**14**) Networking between the Authority and the Member States' organisations operating in the fields within the Authority's mission is one of the basic principles of the Authority's operation. In consequence, in preparing its opinion, the Authority may use the network made available to it by Article 36 of Regulation (EC) No 178/2002 and by Commission Regulation (EC) No 2230/2004 laying down detailed rules for the implementation of Regulation (EC) No 178/2002 with regard to the network of organisations operating in the fields within the European Food Safety Authority's mission[7].

(**15**) 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 in order to protect the competitive position of the applicant**.

(16) Pursuant to Article 41 of Regulation (EC) No 178/2002, Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents[8] applies to documents held by the Authority.

(**17**) Articles 53 and 54 of Regulation (EC) No 178/2002 establish procedures for taking emergency measures in relation to foodstuffs of Community origin or imported from third countries. They authorise the Commission to adopt such measures in situations where foodstuffs are likely to constitute a serious risk to human health, animal health or the environment and where such risk cannot be contained satisfactorily by measures taken by the Member State(s) concerned.

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

(19) Since the objectives of this Regulation cannot be sufficiently achieved by the Member States on account of differences between national laws and provisions and can therefore be better achieved at Community level, the Community may adopt measures in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve these objectives.

(20) 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.**

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7 OJ L 379, 24.12.2004, p. 64.

8 OJ L 145, 31.5.2001, p. 43.

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).**

(21) In particular, power should be conferred on the Commission to update the Community lists of food additives, food enzymes and food flavourings. Since those measures are of general scope and are designed to amend or supplement non-essential elements of each sectoral food law, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

(22) When, on imperative grounds of urgency, the normal time-limits for the regulatory procedure with scrutiny cannot be complied with, the Commission should be able to use the urgency procedure provided for in Article 5a (6) of Decision 1999/468/EC for the removal of a substance from the Community lists and for adding, removing or changing conditions, specifications or restrictions associated with the presence of a substance on the Community lists.

HAVE ADOPTED THIS REGULATION:

CHAPTER I
GENERAL PRINCIPLES

Article 1
Subject matter and scope

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~~ **food** within the Community **and to a high level of protection of human health and protection of consumers' interests**.

   This Regulation shall not apply to smoke flavourings falling within the scope of 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[10].

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.

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10 **OJ L 309, 26.11.2003, p. 1.**

Article 2
Community list of substances

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*.

2. "Updating the Community list" means:

   (a) adding a substance to the Community list;

   (b) removing a substance from the Community list;

   (c) adding or changing conditions, specifications or restrictions associated with the presence of a substance on the Community list.

CHAPTER II
COMMON PROCEDURE

Article 3
Main stages of the common procedure

1. The common procedure for updating the Community list may be initiated either on the initiative of the Commission or following an application. Applications may be made by a Member State or by an interested party, who may represent several interested parties, according to the conditions provided for by the implementing measures referred to in Article 9(1)(a) (hereinafter referred to as "the applicant").

2. The Commission shall seek the opinion of the European Food Safety Authority (hereinafter referred to as "the Authority") in advance, in accordance with Article 5.

   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~~ **human** health.

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

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.

In such cases, ~~where applicable,~~ the Commission **shall make this information public 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.

Article 4
Initiating the procedure

1. On receipt of an application to update the Community list, the Commission:

   (a) shall 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.

   The application shall be made available to the Member States by the Commission.

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.

Article 5
Opinion of the Authority

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

2. The Authority shall forward its opinion to the Commission, the Member States and, where appropriate, the applicant.

Article 6
Additional information concerning risk assessment

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.

2. If the additional information is not sent within the additional period referred to in paragraph 1, the Authority shall finalise its opinion on the basis of the information already provided.

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**, unless there are special reasons for extending the period as referred to in Article 10.**

4. The additional information shall be made available to the Member States by the Authority.

Article 7
Updating the Community list

1. 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.

The regulation updating the Community list shall 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~~ **reasons for its decision**.

2. The regulation shall be adopted in accordance with the **regulatory** procedure **with scrutiny** referred to in Article **14(3)** ~~(2)~~.

3. On imperative grounds of urgency, the Commission may use the urgency procedure referred to in Article 14 (4) for the removal of a substance from the Community list and for adding, removing or changing conditions, specifications or restrictions associated with the presence of a substance on the Community list.

Article 8
Additional information concerning risk management

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 ~~may be extended accordingly~~ **and shall inform the Member States of the extension**.

2. If the additional information is not sent within the additional period referred to in paragraph 1, the Commission shall act on the basis of the information already provided.

CHAPTER III
MISCELLANEOUS PROVISIONS

Article 9
Implementing measures

1. In accordance with the procedure referred to in Article 14(2), within a period of no longer than 24 months from the adoption of each sectoral food law, the implementing measures for this Regulation shall be adopted, and shall concern in particular:

   (a) the content, drafting and presentation of the application referred to in Article 4(1);

   (b) the arrangements for checking the validity of applications;

   (c) the type of information that must be included in the opinion of the Authority referred to in Article 5.

2. With a view to the adoption of the implementing measures referred to in paragraph 1(a), the Commission shall consult the Authority, which, within six months of the date of entry into force of this Regulation, shall present it with a proposal concerning the data required for risk assessment of the substances concerned.

Article 10
Extension of time periods

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 **and the Member States** of the extension and the reasons for it.

Article 11
Transparency

The Authority shall ensure the transparency of its activities in accordance with Article 38 of Regulation (EC) No 178/2002. In particular, it shall make its opinions public without delay. It shall also make public any request for its opinion as well as any time period extension pursuant to Article 6(1).

Article 12
Confidentiality

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

   Information relating to the following shall not, in any case, be considered confidential:

   (a) the name and address of the applicant and the name of the substance;

   (b) a clear description of the substance and the conditions for its use in or on specific foodstuffs or food categories;

   (c) information that is relevant to the assessment of the safety of the substances;

   (d) where applicable, the analysis method(s).

2. So that paragraph 1 can be implemented, applicants shall indicate which of the information provided they wish to be treated as confidential. Verifiable justification must be given in such cases.

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

4. After being made aware of the Commission's position, applicants shall have three weeks in which to withdraw their application so as to preserve the confidentiality of the information provided. Confidentiality is preserved until this period expires.

5. The Commission, the Authority and the Member States shall take the necessary measures to ensure appropriate confidentiality of the information received by them under this Regulation, except for information which must be made public if circumstances so require in order to protect human health, animal health or the environment.

6. If an applicant withdraws, or has withdrawn, its application, the Authority, the Commission and the Member States shall respect the confidentiality of commercial and industrial information, including research and development information, as well as information the confidentiality of which is the subject of disagreement between the Commission and the applicant.

7. The implementation of paragraphs 1 to 6 shall not affect the circulation of information between the Commission, the Member States and the Authority.

Article 13
Emergencies

In the event of an emergency concerning a substance on the Community list, particularly in the light of an opinion of the Authority, measures shall be adopted in accordance with the procedures referred to in Articles 53 and 54 of Regulation (EC) No 178/2002.

Article 14
Committee

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health established by Article 58 of Regulation (EC) No 178/2002.

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

   The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. 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.

4. Where reference is made to this paragraph, Article 5a(1), (2), (4) and (6), and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

~~3. The Committee shall adopt its Rules of Procedure.~~

Article 15
Competent authorities of the Member States

Not later than six months after the entry into force of this Regulation, the Member States shall forward to the Commission and to the Authority, in relation to each sectoral food law, the name and address of the national competent authority for the purposes of the common procedure, as well as a contact point therein.

CHAPTER IV
FINAL PROVISION

Article 16
Entry into force

This Regulation shall enter into force on the twentieth day following its publication in the *Official Journal of the European Union*.

For each sectoral food law, it shall apply from the date of application of the measures referred to in Article 9(1).

Article 9 shall apply from the date of entry into force of this Regulation.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*