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Committee on the Environment, Public Health and Food Safety

15.3.2007 PE 386.368v02-00

AMENDMENTS 27-62

Draft report **(PE 384.475v01-00)**
Åsa Westlund
Common authorisation procedure for food additives, food enzymes and food flavourings

Proposal for a regulation (COM(2006)0423 – C6-0258/2006 – 2006/0143(COD))

Text proposed by the Commission	Amendments by Parliament

Amendment by Åsa Westlund

Amendment 27
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.

Or. en

Justification

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

Amendment by David Martin and Åsa Westlund

Amendment 28
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.

Or. en

Amendment by Mojca Drčar Murko

Amendment 29
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.

Or. en

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 by David Martin and Åsa Westlund

Amendment 30
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 proper cases and for stated reasons.***

Or. en

Amendment by David Martin and Åsa Westlund

Amendment 31
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.

Or. en

Amendment by Avril Doyle

Amendment 32
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 shall, 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).***

Or. en

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 by Carl Schlyter and Bart Staes

Amendment 33
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*** within the Community.

Or. en

Justification

The aim of the regulation should be to ensure a high level of public health and of consumer protection throughout the Community.

Amendment by Horst Schnellhardt

Amendment 34
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.

Or. de

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 by Carl Schlyter and Bart Staes

Amendment 35
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.

Or. en

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 by Horst Schnellhardt

Amendment 36
Article 2, paragraph 1, subparagraph 1 a (new)

Substances authorised 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(6)(a).

Or. de

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 by Mojca Drčar Murko

Amendment 37
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.

Or. en

Amendment by Åsa Westlund

Amendment 38
Article 3, paragraphs 3 and 4

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.
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.
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, where applicable, the Commission shall inform the applicant directly, indicating in its letter the reasons for the update not being considered justified.

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 by Carl Schlyter and Bart Staes

Amendment 39
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	3. The common procedure shall end with the adoption by the Commission of a ***legislative proposal for a regulation of the European***

Article 7.	***Parliament and the Council*** implementing the update.

Or. en

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 by Carl Schlyter and Bart Staes

Amendment 40
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 to the ***European Parliament and the*** Member States by the Commission.

Or. en

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 by David Martin

Amendment 41
Article 4

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) 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.	The application shall be made available to the Member States ***and to stakeholders*** by the Commission.
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 all stakeholders*** and, where applicable, request the opinion of the Authority.

Or. en

Amendment by Carl Schlyter and Bart Staes

Amendment 42
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.

Or. en

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 by Åsa Westlund

Amendment 43
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 nine 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.
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 difference.
The regulation shall be adopted in accordance with the procedure referred to in Article 14(2).	

Or. en

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 by Carl Schlyter and Bart Staes

Amendment 44
Article 7

Within nine months of the Authority giving	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.	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.
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 difference.
The regulation shall be adopted in accordance with the procedure referred to in Article 14(2).	

Or. en

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 by Horst Schnellhardt

Amendment 45
Article 7, subparagraph 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.	Within ***six*** 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.

Or. de

Justification

Following the development of a new substance, businesses should not have to wait more than a year for authorisation. In any case, the necessary flexibility is provided for with regard to lengthy procedures.

Amendment by Ria Oomen-Ruijten

Amendment 46
Article 7, paragraph 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.	Within ***three 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.

Or. en

Justification

1. Regulations 1831/2003 (Feed Additives) and 1829/2003 (GM Food & Feed) both allow three months for the Commission to draft a regulation and propose amendments to the regulations for submission to the Standing Committee on the Food Chain and Animal Health (SCFCAH); Three months instead of the long time-period of nine months, would create consistency with other EU food safety Regulation.
2. A time-period of nine months is a lengthy time-period that will put a heavy and unequal burden on the Small and Medium Sized Enterprises (SME's) ; they usually do not have the resources that large established companies possess and that would give them the luxury to wait for procedures and outcomes (See e.g. also 6.3.1.6 of "Impact Assessment" of "Commission Staff Working Document ; Annex to the Proposal for a Regulation of the European Parliament and of the Council on food enzymes and amending Council directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, and Council Directive 20001/112/EC".)

Amendment by Mojca Drčar Murko

Amendment 47
Article 7, paragraphs 1 and 2

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 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.
Where the draft regulation is not in accordance with the opinion of the Authority, the Commission shall explain the ***difference***.	Where the draft regulation is not in accordance with the opinion of the Authority, the Commission shall explain the ***reasons for its decision***.

Or. en

Justification

Six months for submitting a proposal under the comitology procedure should be sufficient. Reasons for the decision of the Commission should be explained where the draft regulation differs from the opinion of the Authority.

Amendment by Bogusław Sonik

Amendment 48
Article 7, paragraph 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.	Within ***six*** 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.

Or. pl

Justification

The provisions for the common authorisation procedure are unduly lengthy. Following the

six months allocated to the EFSA to give its opinion, the Commission then proposes to take nine months to submit a proposal under the comitology procedure. Six months in this respect should be sufficient.

Amendment by Avril Doyle

Amendment 49
Article 7, paragraphs 1 and 2

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 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.
Where the draft regulation is not in accordance with the opinion of the Authority, the Commission shall explain the ***difference***.	Where the draft regulation is not in accordance with the opinion of the Authority, the Commission shall explain the ***reasons for its decision.***

Or. en

Justification

The provisions for the common authorisation procedure are unduly lengthy. Following the 6 months allocated to EFSA to give its opinion, the Commission then proposes to take 9 months to submit a proposal under the Comitology procedure. Six months in this respect should be sufficient.

Amendment by Horst Schnellhardt

Amendment 50
Article 7, subparagraph 2 a (new)

	If the Commission does not ask the Authority for an opinion, the period referred to in paragraph 1 shall begin from the moment a valid application is submitted

to the Commission.

Or. de

Justification

The deadline should be clearly stated even in the case of registrations, for which an opinion from the Authority is not required.

Amendment by Mojca Drčar Murko

Amendment 51
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***.

Or. en

Amendment by Carl Schlyter and Bart Staes

Amendment 52
Article 8, paragraph 2

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.***	2. If the additional information is not sent within the additional period referred to in paragraph 1, the Commission shall ***extend the period provided for in Article 7 or reject the application.***

Or. en

Justification

If the applicants do not supply data requested within a reasonable time frame, the Commission should be given more time for the assessment.

Amendment by Mojca Drčar Murko

Amendment 53
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.

Or. en

Justification

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

Amendment by Horst Schnellhardt

Amendment 54
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 of the extension and the reasons for it.

Or. de

Justification

The applicant should always be informed of any extension of the time limit. To be able to

plan, applicants need to be informed of an extension in good time and of the reasons for it.

Amendment by David Martin

Amendment 55
Article 11

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).	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, ***together with all applications and related material***. It shall also make public any request for its opinion as well as any time period extension pursuant to Article 6(1).

Or. en

Amendment by Mojca Drčar Murko

Amendment 56
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.

Or. en

Justification

Member states should also be informed.

Amendment by Horst Schnellhardt

Amendment 57
Article 12, paragraph 3

3. ***The*** Commission shall decide which information can remain confidential and	3. ***After consulting the applicant, the*** Commission shall decide which information

notify applicants accordingly.	can remain confidential and notify applicants accordingly.

Or. de

Justification

The applicant should have the right to be informed of the decision at an early opportunity. Producers should also be able to present their point of view and give their opinion on the Commission's position.

Amendment by Ria Oomen-Ruijten

Amendment 58
Article 12, paragraph 3

3. The Commission shall ***decide*** which information can remain confidential ***and notify applicants accordingly***.	3. The Commission shall ***determine, together with the applicant,*** which information can remain confidential.

Or. en

Justification

Involvement from - and interaction with the applicant to determine which information can remain confidential, is essential in the earliest stage of the procedure ; Only then the confidentiality of information, that may in its total combination otherwise potentially harm the commercial interests or interests on scientific research and development of the applicant, is guaranteed.

Amendment by Ria Oomen-Ruijten

Amendment 59
Article 12, paragraph 4

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.	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 ***or introduce an appeal against the Commission's position. The Commission shall then have a period of two months in***

	which to take a final decision on the appeal. Confidentiality is preserved until ***the initial three-week*** period expires ***or, in the case of an appeal, until the final decision is taken.***

Or. en

Justification

To create a right of appeal for applicants towards the decisions of the Commission related to the confidentiality of information.

Amendment by Ria Oomen-Ruijten

Amendment 60
Article 12, paragraph 6

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***.	6. If an applicant withdraws, or has withdrawn, its application, the Authority, the Commission and the Member States shall respect the confidentiality of ***all the information provided in the application.***

Or. en

Justification

In order to protect the potential harm to the commercial interests or interests on scientific research and development of the applicant, it is essential to ensure the protection of the interests of the applicant by keeping all the information in the application and in its total combination, confidential.

Amendment by Horst Schnellhardt

Amendment 61
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 ten 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.

Or. de

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 by Ria Oomen-Ruijten

Amendment 62
Article 12, paragraph 7 a (new)

7a. Scientific data and other information provided by applicants may not be used for the benefit of a subsequent applicant for a period of ten 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.

Or. en

Justification

1. In order to stimulate Research and Development within the food additive industry, it is appropriate to protect proprietary data that result from investment made by innovators for the gathering of the information and data that support the application under this Regulation. This protection however should be limited in time in order to avoid unnecessary duplication of studies, repetition of animal testing and not to impair competition.
2. A time period of 10 years in order to protect proprietary data would create consistency with the other EU food safety legislation 1829/2003 (GM Food & Feed), where Article 31 states that "The scientific data and other information in the application may not be used for the benefit of another applicant for a period of 10 years from the date of authorisation, unless the other applicant has agreed with the authorisation holder."