Basic information

2006/0144(COD) COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	Procedure completed
Food enzymes Amending Regulation (EC) No 258/97 1992/0426(COD) Amending Directive 2001/112/EC 1996/0115(CNS) Amending Regulation (EC) No 1493/1999 1998/0126(CNS) Amending Directive 2000/13/EC 1999/0090(COD) **Subject** 3.10.10 Foodstuffs, foodstuffs legislation 3.40.13 Food industry 4.60.02 Consumer information, advertising, labelling 4.60.04.04 Food safety	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
ENVI Environment, Public Health and Food Safety	DOYLE Avril (PPE-DE)	14/09/2006

Former committee responsible	Former rapporteur	Appointed
ENVI Environment, Public Health and Food Safety	DOYLE Avril (PPE-DE)	05/10/2006

Former committee for opinion	Former rapporteur for opinion	Appointed
ITRE Industry, Research and Energy	HENNICOT-SCHOEPGES Erna (PPE-DE)	04/10/2006
IMCO Internal Market and Consumer Protection	The committee decided not to give an opinion.	
AGRI Agriculture and Rural Development	The committee decided not to give an opinion.	

Former committee for opinion on the legal basis	Former rapporteur for opinion	Appointed
JURI Legal Affairs	MEDINA ORTEGA Manuel (PSE)	26/02/2007

Council of the European Union	Council configuration	Meetings	Date
	General Affairs	2858	2008-03-10
	Employment, Social Policy, Health and Consumer Affairs	2803	2007-05-30
	Agriculture and Fisheries	2841	2007-12-17
	Agriculture and Fisheries	2904	2008-11-18

Key events

Date	Event	Reference	Summary
28/07/2006	Legislative proposal published	COM(2006)0425	Summary
05/09/2006	Committee referral announced in Parliament, 1st reading		
08/05/2007	Vote in committee, 1st reading		Summary
11/05/2007	Committee report tabled for plenary, 1st reading	A6-0177/2007	
30/05/2007	Debate in Council		Summary
09/07/2007	Debate in Parliament		
10/07/2007	Decision by Parliament, 1st reading	T6-0322/2007	Summary
10/07/2007	Results of vote in Parliament		
24/10/2007	Modified legislative proposal published	COM(2007)0670	Summary
10/03/2008	Council position published	16676/1/2007	Summary
13/03/2008	Committee referral announced in Parliament, 2nd reading		
06/05/2008	Vote in committee, 2nd reading		Summary
13/05/2008	Committee recommendation tabled for plenary, 2nd reading	A6-0176/2008	
07/07/2008	Debate in Parliament		
08/07/2008	Decision by Parliament, 2nd reading	T6-0332/2008	Summary
08/07/2008	Results of vote in Parliament		
18/11/2008	Act approved by Council, 2nd reading		
16/12/2008	Final act signed		
16/12/2008	End of procedure in Parliament		
31/12/2008	Final act published in Official Journal		

Technical information

Procedure reference	2006/0144(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation

Legislative instrument	Regulation
Amendments and repeals	Amending Regulation (EC) No 258/97 1992/0426(COD) Amending Directive 2001/112/EC 1996/0115(CNS) Amending Regulation (EC) No 1493/1999 1998/0126(CNS) Amending Directive 2000/13/EC 1999/0090(COD)
Legal basis	EC Treaty (after Amsterdam) EC 095 EC Treaty (after Amsterdam) EC 037
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/6/58916

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee draft report		PE386.295	07/03/2007	
Committee opinion	ITRE	PE384.272	28/03/2007	
Committee opinion	JURI	PE388.556	03/05/2007	
Committee report tabled for plenary, 1st reading/single reading		A6-0177/2007	11/05/2007	
Text adopted by Parliament, 1st reading/single reading		T6-0322/2007	10/07/2007	Summary
Committee draft report		PE402.788	05/03/2008	
Amendments tabled in committee		PE404.627	03/04/2008	
Committee recommendation tabled for plenary, 2nd reading		A6-0176/2008	13/05/2008	
Text adopted by Parliament, 2nd reading		T6-0332/2008	08/07/2008	Summary

Council of the EU

Document type	Reference	Date	Summary
Council position	16676/1/2007	10/03/2008	Summary
Draft final act	03659/2008/LEX	16/12/2008	

European Commission

Document type	Reference	Date	Summary
Legislative proposal	COM(2006)0425	28/07/2006	Summary
Document attached to the procedure	SEC(2006)1044	28/07/2006	
Document attached to the procedure	SEC(2006)1045	28/07/2006	
Commission response to text adopted in plenary	SP(2007)4170	29/08/2007	
	COM(2007)0670		

Modified legislative proposal		24/10/2007	Summary
Commission communication on Council's position	COM(2008)0144	11/03/2008	Summary
Commission opinion on Parliament's position at 2nd reading	COM(2008)0607	17/10/2008	Summary

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
EESC	Economic and Social Committee: opinion, report	CES0604/2007	25/04/2007	

Additional information

Source	Document	Date
National parliaments	IPEX	
European Commission	EUR-Lex	

Final act

Regulation 2008/1332
OJ L 354 31.12.2008, p. 0007 Summary

Food enzymes

2006/0144(COD) - 10/03/2008 - Council position

The common position introduced a number of modifications to the text, many of which were based on, and inspired by, Parliamentary amendments tabled at first reading. The Council, on its own initiative, introduced some of the Parliamentary amendments in each of the three sectoral proposals, with a view to harmonising the provisions. The common position incorporates in full, or in principle, 21 of the 33 amendments proposed by Parliament at first reading.

In summary, the main elements of the common position are as follows:

A single legal base: accepting Parliamentary suggestions, the Council has decided to retain Article 96 of the TEU as the sole legal base for the proposal agreeing that agricultural aspects are merely incidental and not core to the proposed Regulation's objectives.

Misleading the consumer: the provisions relating to misleading the consumer have been integrated into recital 6 of the proposal.

Protecting the environment: the Council has modified the proposal so that prior to an authorisation being granted, scientific evaluators should take any environmental impacts into consideration.

Regulatory comitology procedure with scrutiny: the Council has agreed to introduce the new regulatory procedure with scrutiny for the adoption of measures that supplement the Regulation.

Interpretation decisions: all provisions relating to interpretations have been regrouped into a new single article. Given that they do not supplement the Regulation they have been made subject to the regulatory comitology procedure without scrutiny.

Transitional measures for products already on the market: in the common position, the Council has provided for a one year transitional period, from the date of entry into force of the proposed Regulation. Foods lawfully placed on the market or labelled during this year may be marketed until their date of minimum durability or use-by-date.

Provisions prohibiting the placing on the market of non-compliant food enzymes: For reasons of clarity, legal certainty and the correct functioning of the internal market, the Council has inserted an article that prohibits producers from placing non-compliant food enzymes on the market. This is consistent with the proposals concerning flavourings and food additives.

Authorisation of enzymes falling within the scope of Regulation (EC) No 1829/2003 on genetically modified food and feed: the Council agrees, subject to some redrafting, that the two authorisation procedures for any substance can be carried out simultaneously.

Labelling: Labelling provisions have been streamlined and reinforced. A distinction is drawn between “business to business” labelling and labelling requirements for products intended for sale to the final consumer. Although the order of provisions is different from that proposed by Parliament, the principles underlying the content are the same.

Amendments not incorporated into the common position:

Enzymes added to food for nutritional purposes and digestive aids: the Council has decided that it is unnecessary to make an explicit reference to enzymes intended for human consumption (such as enzymes used for nutritional purposes or as digestive aids) given that they are excluded from the scope of the proposed Regulation. In fact, the scope of the proposed Regulation only includes enzymes added to food to perform a technological function. Based on this logic, the Council has therefore also decided to exclude cultures that are “traditionally” used in the production of food (such as cheese and wine) and which may incidentally produce enzymes. By deleting the word “traditionally” the scope for exclusion would be enlarged and could result in cultures which, are added to food for the technological function of the enzyme that they produce, not being adequately regulated.

Enzymes that benefit the consumer: the Council has decided not include this amendments on the grounds that the proposed Regulation covers enzymes that are added to food for a technological function and hence the use of enzymes in most cases improves the environmental performance of the production process, which brings an indirect rather than direct benefit for the consumer.

GMOs – Labelling: given that food enzymes remain subject to labelling provisions defined in Directive 2000/13 relating to the labelling, presentation and advertising of food stuffs, as well as Regulation (EC) No 1829/2003 on genetically modified food and feed, the Council decided to adopt a prudent approach and did not accept amendments that could interfere with the scope of the horizontal Regulations already in force.

GMOs – Unique identifier: on the grounds of proportionality and simplification, the Council has deleted any reference requiring enzyme specification in the Community list of food enzymes, since this is considered superfluous.

Precautionary principle: the precautionary principle is a general principle that underlies general food law and as a result applies to the proposed Regulation with no need for a specific reference to it. Moreover, in the risk analyses framework, the precautionary principle can only be taken into account within the context of risk management, never in the risk assessment phase – as suggested by Parliament.

Publication of the opinions of the European Food Safety Authority (EFSA): given that publication of EFSA opinions is already provided for in Regulation (EC) No 178/2002, the Council considered this amendment superfluous.

Re-evaluation every 10 years: the Council considers that a system of continuous observation and re-evaluation provides adequate food safety. An additional review every 10 years would represent an unnecessary administrative burden on producers, users, the EFSA, the Commission and the Member States.

Decisions submitted to the comitology procedure without scrutiny: Decisions on whether or not a given substance falls within the scope of the proposed Regulation are interpretive in nature and will not supplement the Regulation. As a result they do not fall within the scope of the regulatory procedure with scrutiny.

Definition of enzymes: An additional definition of “enzymes” when “food enzymes” is already defined is not, in the Council’s opinion, necessary.

Specification of the entries of food enzymes in the list: the Council decided to maintain the phrase “where necessary” when providing for certain specifications. The need for such labelling concerns a restricted number of cases only, where the physical composition of the food has been changed due to the use of a food enzyme. In such cases only should the consumer be informed of the fact.

Labelling: although the Chapter of Labelling has been reorganised by the Council, the principles underlying the provision’s content remain the same. However, in cases where provisions are already established in other EU legislative acts, they have not been adopted in the common position. For example, Parliament’s proposal requiring labels to provide information on the side-effects of enzymes in excessive quantities has not been included on the grounds that the EFSA already took such information into account during the revaluation procedure. Further, information on the technological function of an enzyme, as proposed in one Parliamentary amendment would, according to the Council, be of little use to non-specialists.

To conclude, the Council is of the view that the common position represents a fair balance of concerns and interests that respects the proposed Regulation’s objectives.

Food enzymes

2006/0144(COD) - 08/07/2008 - Text adopted by Parliament, 2nd reading

The European Parliament adopted a legislative resolution amending the Council’s common position for adopting 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, Council Directive 2001/112/EC and Regulation (EC) No 258/97. The recommendation for second reading (under the codecision procedure) had been tabled for consideration in plenary by Avril **DOYLE** (EPP-ED, IE) on behalf of the Committee on the Environment, Public Health and Food Safety.

The amendments were the result of a compromise between the Council and the Parliament. The main amendments – adopted under the 2nd reading of the codecision procedure – are as follows:

- the risk assessments of the Authority for individual enzymes should be published as soon as they are completed;

- Parliament stressed that the objectives are the effective functioning of the internal market, a high level of protection of human health and a high level of consumer protection;

- Parliament clarified the notion of misleading the consumer. This includes, but is not limited to, issues related to the nature, freshness and quality of ingredients used, the naturalness of a product or of the production process, or the nutritional quality of the product;

- a recital the precautionary principle should be part of any assessment;

- where a food enzyme already included in the Community list is produced from a different source falling within the scope of Regulation (EC) No 1829 /2003, it will not require a new authorisation under this Regulation, as long as the new source is covered by an authorisation in accordance with Regulation (EC) No 1829/2003 and the food enzyme complies with the specifications established under this Regulation;

- in terms of labelling requirements, Parliament felt that the wording 'a sales description which includes the name of each food enzyme' should be replaced by the nomenclature of the International Union of Biochemistry and Molecular Biology (IUBMB).

Food enzymes

2006/0144(COD) - 10/07/2007 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted a resolution drafted by Avril **DOYLE** (EPP, IE), and made some amendments to the proposal, stipulating stricter conditions of use by introducing the precautionary principle as a rule of conduct. The main amendments were as follows:

- legal base: whereas the Commission’s proposal cited two legal bases Articles 37 and 95, Parliament stated that Article 95 should be the sole legal base;

- scope: this Regulation will not apply to: (a) microbial cultures that are used in the production of food and which may incidentally produce enzymes but which are not specifically used to produce them; (b) enzymes intended for direct human consumption, such as enzymes for nutritional purposes or enzymes used as digestive aids. A new clause states that no person shall place on the market a food enzyme or any food in which such a food enzyme is present if the use of the food enzyme does not comply with the Regulation;

- precautionary principle: a food enzyme may be included in the Community list only if it meets the following conditions: it does not, on the basis of the scientific evidence available and the precautionary principle , pose a safety concern to the health of the consumer at the level of use proposed; there is a reasonable technological need; its use does not mislead the consumer; misleading the consumer includes, but is not limited to, issues related to the nature, freshness and quality of ingredients used, the naturalness of a product or of the production process, the nutritional quality of the product or the fruit and vegetable content; its use has a clear benefit for the consumer;

- EFSA: the opinions of the Authority should be published as soon as the scientific assessment is completed, before the Community list is drawn up. A fresh scientific evaluation and classification should be performed at least every 10 years. The Authority shall be allowed to decide on a "fast track" authorisation procedure for food enzymes which are currently on the market if the Authority is satisfied that they have undergone an adequate safety assessment at national or Community level within the EU so that such enzymes could be directly transposed to the Community list of food enzymes; any appropriate transitional measures may be adopted in accordance with the regulatory procedure with scrutiny;

- comitology: it may be decided in accordance with the regulatory procedure with scrutiny whether or not a given substance falls within the scope of this Regulation. Parliament also stipulated that various implementing rules must be made in accordance with the regulatory procedure with scrutiny;

- definitions: Parliament inserted definitions for “enzyme”, “food enzyme preparation”, "produced by GMOs" and “quantum satis”; it amended the definition for “food enzyme”. It stated, in addition, that the most accurate enzyme name should be used, including its common or recommended name, systematic name and synonyms, if possible according to the nomenclature of the International Union of Biochemistry and Molecular Biology and, in the case of complex enzymes, selected on the basis of the enzyme activity that determines the enzyme's function;

- Parliament clarified that a food enzyme falling within the scope of Regulation (EC) No 1829/2003 and not already included in the Community list may be included in that list in accordance with this Regulation only if it is covered by an authorisation in accordance with Regulation (EC) No 1829/2003;

- labelling: Parliament provided that food enzymes and food enzyme preparations not intended for sale to the final consumer, whether sold singly or mixed with each other, may be marketed only if the packaging or containers provide certain prescribed information. Enzymes or foods containing food enzymes intended for sale to the final consumer may be marketed only if their packaging contains certain information, inter alia, the name under which the food enzyme is sold or both that name and the technological function in the food; and where applicable, an indication that the product contains **genetically modified organisms** or substances produced from them. In addition, information about all enzymes used in the production process should be made available to consumers, if not on the label then at least through other information channels, with priority assigned to those at the point of sale. Moreover, provision should also be made for consumers to access this information from home, for example over the Internet or by means of telephone hotlines;

Lastly, enzymes present in the food product must be designated by the name of one of the categories of ingredients listed in Annex II, followed by their specific name and an indication of whether they are still active in the final product or not; for enzymes produced from GMOs the indication "produced from GMOs" shall be given on the label.

Food enzymes

2006/0144(COD) - 11/03/2008 - Commission communication on Council's position

The Commission supports the common position, adopted by the Council in March 2008 given that it is in line with the initial proposal. Further, the common position takes on board a number of amendments proposed by Parliament at first reading.

Amendments accepted by the Commission:

Legal base: The common position deletes Article 37 of the Treaty as the legal base for the proposal and thus is fully in line with an amendment made by Parliament during first reading.

Criteria for the authorisation of food enzymes: The common position clarifies what is meant by misleading the consumer and takes account of Parliamentary concerns.

Definitions: A definition on “food enzyme preparation” reflects that of a Parliamentary proposal. Further, the new Article 5 of the common position clarifies that a food enzyme or a food in which an enzyme is used should not be placed on the market, if the enzyme or its use does not comply with the proposed Regulation. This was a clarification sought by the European Parliament.

Interplay with Regulation (EC) No 1829/2003 on GM food and feed: The common position has adopted Parliamentary amendments that the evaluation and authorisation procedures under the two Regulations should run simultaneously.

Regulatory procedure with scrutiny: The Council has agreed to use the “regulatory procedure with scrutiny” and to align, in general, the proposed Regulation with that of Council Decision 2006/512/EC laying down procedures for the exercise of implementing powers conferred on the Commission.

Labelling of food enzymes sold from business to business or directly to final consumer: The common position has adopted, albeit with slightly different wording, many of the amendments adopted by Parliament at first reading relating to the labelling of food enzymes. Two elements, however, have not been adopted by the Council. They concern, information on the “side effects of their use in excessive quantities” and a requirement that “food enzymes be added to foods only in a dose strictly necessary to achieve the purpose for which they are used.” In addition, the common position has gone further in simplifying the labelling provisions, given that these enzymes are considered to be food and hence covered by the labelling provisions of Directive 2000/13/EC.

Novel Foods: A Parliamentary amendment that seeks to amend the Novel Food Regulation, in order to clarify that food enzymes are excluded from the scope of that Regulation, has been endorsed by Council.

Transitional measures: An amendment on additional transition measures has been accepted, in full, and incorporated into the common position.

Amendments not incorporated in the common position, but accepted by the Commission:

Definitions: Parliamentary amendments that improve, from a technical point of view the term “enzyme” have been incorporated in the Commission’s amended proposal.

Enzymes used for nutritional purposes or enzymes used as digestive aids: The Commission has decided to fully incorporate a Parliamentary amendment clarifying that the proposed Regulation will not apply to food enzymes intended for direct human consumption, such as enzymes for nutritional purposes or enzymes used as digestive aids. This clarification is fully in line with the Commission’s initial proposal and has therefore been endorsed. The Council, however, has not introduced a similar clarification in its common position.

Fast track authorisation: On the matter of food enzymes which are already on the market, Parliament proposed to transfer them directly onto the Community list through a fast track authorisation procedure – on condition that the EFSA is satisfied with the previous safety assessment carried out at either Community or national level. The Commission is of the view that an automatic transfer of food enzymes on to the Community list (without a previous evaluation by the EFSA) would not be appropriate. In short, therefore, the Commission has decided to accept the amendment subject to some rewording clarifying that the EFSA should consider existing opinions as part of their evaluation.

New provisions introduced by Council:

Scope: In its common position, the Council decided to exclude food enzymes used exclusively in the production of processing aids, from the scope of the proposed Regulation. What it does include in the scope though are enzymes used in the production of novel foods and in the production of flavourings. The Commission is of the view, however, that most of the enzymes used in the production of flavourings seem to be the same as the enzymes used in other foods. As a result, the Parliamentary amendment would not have a major practical impact, considering the small number of enzymes involved.

Different production methods: The Commission has accepted a new requirement, set out in the common position, concerning enzymes produced from different production methods. The Commission agrees that they should be evaluated for their safety before they can be used.

Environment: The Council has clarified the principle that the rules on food enzymes should ensure the effective functioning of the internal market as well as offering a high level of protection to human health and the environment. The Commission has accepted this change.

Interplay of the proposed Regulation with Regulation (EC) No 1830/2003: With regard to the unique identifier attributed to a GMO, the EP clarified the relevant provision of the proposal. The Commission has decided to accept this clarification. Similarly, the Commission has accepted a Council deletion on provisions relating to the unique identifier from recital 8 and Article 7(2).

Interpretation decisions: The common position includes a new Article 9 to provide, where necessary, for “interpretation decisions” under the regulatory procedure on matters concerning whether a given substance is a food enzyme or if a particular food belongs to a food category in the Community list.

To conclude, the Commission is of the view that the common position fully reflects the key elements of its initial proposal as well as adopting many of the amendments made by Parliament at first reading. The Commission therefore agrees with the common position, as adopted unanimously by the Council.

Food enzymes

2006/0144(COD) - 17/10/2008 - Commission opinion on Parliament's position at 2nd reading

The European Parliament voted, in second reading, a consolidated text which contains a number of amendments to the text of the common position. The text is the result of negotiations between the Council, the EP and the Commission. All amendments are mainly of technical nature and are in line with the key principles of the initial proposal.

The most important amendments concern the clarification of the interplay between the proposed Regulation on enzymes and Regulation (EC) No 1829 /2003 on genetically modified food and feed. Two other amendments strengthen the precautionary principle and further clarify the principle of not misleading the consumer.

The Commission **accepts all the amendments** voted by the European Parliament and amends its proposal as set out above.

Food enzymes

2006/0144(COD) - 16/12/2008 - Final act

PURPOSE: to authorise the use of food enzymes at Community level.

LEGISLATIVE ACT:Regulation (EC) No 1332/2008 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, Council Directive 2001/112/EC and Regulation (EC) No 258/97.

CONTENT: the Council adopted a Regulation on food enzymes following agreement reached with the Parliament at second reading. Previously, Community legislation only covered enzymes used as food additives. The remaining enzymes were not regulated at all or were regulated as processing aids under the legislation of the Member States, which is diverse. With respect to safety, there was neither safety evaluation nor authorisation of food enzymes at Community level, except for those that were considered as food additives. This Regulation aims to establish harmonised rules for food enzymes at Community level, in order to promote fair trading and effective functioning of the internal market and to ensure protection of human health and consumers' interests.

The Regulation provides for:

- a Community list of approved food enzymes;
- conditions of use of food enzymes in foods;
- rules on the labelling of food enzymes sold as such.

A food enzyme may be included in the Community list only if it meets the following conditions and, where relevant, other legitimate factors:

- it does not, on the basis of the scientific evidence available, pose a safety concern to the health of the consumer at the level of use proposed;
- there is a reasonable technological need, and
- its use does not mislead the consumer. Misleading the consumer includes, but is not limited to, issues related to the nature, freshness and quality of the ingredients used, the naturalness of a product or of the production process, or the nutritional quality of the product.

The Regulation applies to enzymes which are added to food to perform a technological function in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food.

The Commission will consider whether a food enzyme should be included on the positive list on the basis of a scientific assessment by the European Food Safety Authority.

Parliament’s amendments at second reading mainly concerned the clarification of the interplay between the Regulation and Regulation (EC) No 1829 /2003 on genetically modified food and feed.

A food enzyme which falls within the scope of Regulation (EC) No 1829/2003 on genetically modified food and feed should be authorised in accordance with that Regulation as well as under this Regulation.

The approval of food enzymes should also take into account societal, economic, traditional, ethical and environmental factors and the feasibility of controls.

It should be noted that the Regulation forms part of the package of proposals on 'food improvement agents'. This package of proposals refers to food flavourings, and food additives. It contributes to the Commission's simplification programme and also provides for harmonisation not only in their respective fields but also promotes consistency between the three related areas. An additional fourth act within the package will establish a single common authorisation procedure for the evaluation and approval of these substances (COD/2006/0143.)

ENTRY INTO FORCE: 20/01/2009.

APPLICATION: the provision regarding the Community list of food enzymes will apply from the date of application of the Community list. Until that date, national provisions in force concerning the placing on the market and use of food enzymes and food produced with food enzymes shall continue to apply in the Member States.

The Chapter on Labelling will apply from 20/01/2010.

Food enzymes

2006/0144(COD) - 17/12/2007

The Council reached an overall political agreement on a legislative package on food improvement agents (food additives, food enzymes and food flavourings).

After finalisation of the text, a common position will be adopted at a forthcoming Council meeting and forwarded to the European Parliament for a second reading, in accordance with the codecision procedure.

Food enzymes

2006/0144(COD) - 24/10/2007 - Modified legislative proposal

The Commission has amended its initial proposal to take account of Parliamentary amendments adopted under the first reading. To recall, Parliament adopted 33 amendments in total of which most were accepted by the Commission either in whole or in part, subject to some rewording. Seven were not adopted.

In summary, the Commission modified its proposals as follows:

Technical/ Editorial amendments: Amendments deemed to improve, from a technical and editorial point of view, the proposal have been adopted by the Commission. They include, in particular, an amendment concerning Regulation (EC) No 258/97 on novel foods which seeks to clarify that food enzymes, which are covered by the proposed Regulation on food enzymes will be excluded from the scope of the novel food Regulation.

Legal Basis: The Commission has agreed to delete Article 37 from the TEU as the legal basis of the proposed Rewgulation given that agricutlrual aspects of the proposal are a secondary objective only.

Scope: The Commission has accepted amendments (with some re-working regarding their positioning in the text) that clarify the proposal will not apply to food enzymes intended for direct human consumption, such as enzymes for nutritional purposes or enzymes used as digestive aids. The principle of these amendments is in line with the Commission proposal. The Commission, however retains the exclusion of cultures that are "traditionally" use in the production of foods such as cheese, wine etc and which may incidentally produce enzymes. The deletion of the word "traditionally" would enlarge the scope to the exclusion and could result in cultures, which are added to food for the technological function of the enzyme that they produce (e.g. preservation) not being regulated.

Definitions: The new definitions (as proposed by Parliament) on "enzyme" and "food enzyme preparation" have been adopted with some editorial changes. However, the definition of "produced by GMOs" is considered unnecessary for the scope of the proposed Regulation which covers all food enzymes regardless of whether it falls into the scope of Regulation (EC) No 1829/2003. The Commission, as a result, has not incorporated the new definition into the amended proposal. Similarly, the Commission has not included the definition of *"quantium satis*" in the proposal given that it is a repetition of provisions set down in the proposal for "food additives".

Prohibition of non-compliant food enzymes: An amendment stating that a food enzyme or a "food in which an enzyme is used", should not be placed on the market in cases where they do not comply with the proposed Regulation, has been endorsed by the Commission.

General criteria for inclusion and use of food enzymes in the Community list. Amendments relating to misleading the consumer have been incorporated into the revised proposal. Amendments concerning: authorisation of food enzymes based on the precautionary principles and requiring food enzymes to bring a clear benefit to the consumer before they can be authorised, however, have not been adopted.

Proposals relationship with GM food and feed: The Commission endorses an amendment clarifying that two GMO procedures can run simultaneously and in accordance with good administrative practice.

Comitology: The Commission has agreed to modify its initial proposal so that the implementing powers will be in line with Decision 2006/512/EC – the new regulatory procedure with scrutiny. An amendment which would apply the new regulatory procedure with scrutiny to deciding whether or not a given substance falls within the scope of the Regulation, however, has not. The normal regulatory procedure should apply in the later case.

10 Year review: An amendment requiring a ten year review has not been accepted by the Commission on the grounds that it would impose a significant administrative burden.

Fast track authorisation: An amendment whereby enzymes, which are already on the market, could be transferred direct to the Community list, if the EFSA is satisfied with the previous safety assessment carried out at Community or national level, has not been adopted. The Commission has, however, introduced new wording that clarifies the EFSA could consider existing opinions as part of their evaluation.

Labelling: The Commission has taken over the main ideas concerning the simplification of labelling provisions sold from business to business or to the final consumer. However, the provisions requiring information on the "side-effects of their use in excessive quantities" is deemed irrelevant and therefore has not been adopted. An amendment requiring that food enzymes should be added to foods only in a dose which is strictly necessary has been incorporated into the revised proposal on the grounds that it is in line with the *quantum satis* principle. A further amendment, which was not accepted by the Commission, refers to requiring the labelling of the technological function of the food enzyme sold directly to the final consumer.

Labelling of food enzymes in food: The Commission has decided not to accept two amendments concerning the labelling of food enzymes in food. Specifically they refer to i) introducing labelling of all food enzymes present in the final food, irrespective of the level of residues and whether they continue to function or not and ii) requiring information on all food enzymes used in the production process to be made available to consumers – if not on the label at least through other information channels. The Commission has decided not adopt these amendments given that they are not compatible with Directive 2000/13/EC.

Transitional measures: The Commission has endorsed an amendment that introduces transitional measures for food enzymes, food enzyme preparations and food containing food enzymes, which were put on the market or labelled before the date of application.

Changes to production process or starting materials of a food enzyme. **New Article 8**: The amended Commission proposal includes a new Article 8 introducing requirements for food enzymes already included in the Community list which are prepared by production methods or starting material significantly different form those included in the risk assessment of the Authority. This Article reflects the principle of the initial Commission proposal and is consistent with the proposal on food additives, where the same text has been introduced in order to address an amendment concerning "nano" substances.

Food enzymes

2006/0144(COD) - 30/05/2007

Pending the European Parliament first reading opinion, the Council reached general approaches on three draft Regulations concerning: common authorisation procedure; food additives; food enzymes. It took note of a progress report regarding a draft Regulation on flavourings.

Food enzymes

2006/0144(COD) - 28/07/2006 - Legislative proposal

PURPOSE: to authorise the use of food enzymes at Community level.

PROPOSED ACT: Regulation of the European Parliament and of the Council

CONTENT: this Commission proposal is being forwarded to the Parliament and the Council within the context of the White Paper on Food Safety and alongside three other related proposed Regulations. They are on:

- Establishing a common authorisation procedure for food additives, food enzymes and food flavourings. (for a summary refer to COD/2006 /0143)
- Food additives; (for a summary refer to COD/2006/0145)
- Certain food ingredients with flavouring properties for use in and on food. (For a summary refer to COD/2006/0147).

Enzymes are currently authorised based on the principles established Directive 89/107/EEC and are classified as a "food additive". Only 2 of the estimated 200 enzymes on the market are classified this way. The remaining are either not regulated at all or are regulated as "processing aids" under national law. The present situation is such that, at a Community level, there is scant provision for the regulation of enzymes, whilst at a national level, the provisions that do exist vary considerably resulting in a fragmented market.

Although, historically speaking, enzymes are deemed non-toxic, the development of food enzymes in recent years has expanded considerably, resulting in complex and sophisticated processing techniques. Experts warn of potential hazards arising from their chemical make-up such as allergenicity, activity-related toxicity, residual microbiological activity and chemical toxicity.

The purpose of this proposal, therefore, is two-fold. Firstly, it is designed to create harmonised standards applicable across the internal market and secondly, to offer a high level of consumer protection. In order to achieve these objectives, the proposed Regulation sets the conditions for the use of food enzymes; for a positive list of Community approved enzymes; and labelling requirements.

The Regulation will apply to enzymes used for a *technological purpose* in the manufacture, processing, preparation, treatment, packaging, transport or storage of food, including enzymes used as *processing aids.* A distinction is made between enzymes used for a *technological purpose* and enzymes used as *processing aids* when it comes to labelling requirements, with the later group being exempt.

The Commission proposes that all food enzymes be evaluated for their safety, technological need and benefits. Safety evaluations will be carried out by the European Food Safety Authority (EFSA). As far as the labelling requirements are concerned it is proposed that food enzymes be classified as

ingredients, along the same lines as additives are classified in Directive 2000/13/EC relating to the labelling, presentation and advertising of foodstuffs. In most cases, food enzymes will be used as processing aids (i.e. they will be present in food in the form of a residue, if at all) and hence have little or not effect on the finished product. Hence, this category of enzyme will not be subject to the food labelling requirements. Food enzymes used to exert a technological function in the final food (such as stabilisers) however, will have to label their specific name and function.

Producers of food enzymes will be obliged to inform the Commission of any new information which may affect the safety assessment of the food enzyme. Implementation will be based on the regulatory procedure. In order to allow manufacturers and producers of food enzymes time to adjust to the new legislation, the Commission is proposing an initial period of 24 months (following the date of application), during which applications can be submitted.

Lastly, the Community list will be established in a “single-step” procedure following an opinion on all products from the EFSA and within the 24 month submission period. Until the finalisation of the list food enzymes and products already on the market may be used in accordance with national rules. A transitional period is also foreseen for the labelling requirements.

The proposal will have some impact on the Community’s budget. In order to develop and update Community legislation on food enzymes, in a proportionate and effective way, studies and the collection of data will need to be undertaken. Support for such action is foreseen by Regulation 882 /2004/EC on official feed and food controls and is within the amounts set aside for the 2007/2013 period.