Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	2006/0145(COD)
Food additives Repealing Directive 95/2/EC 1992/0424(COD) Repealing Decision No 292/97/EC 1995/0085(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	Procedure completed

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
ENVI Environment, Public Health and Food Safety	PSE WESTLUND Åsa	14/09/2006
Former committee responsible		
ENVI Environment, Public Health and Food Safety	PSE WESTLUND Åsa	14/09/2006
Former committee for opinion		
ITRE Industry, Research and Energy	The committee decided not to give an opinion.	
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		
JURI Legal Affairs	PSE MEDINA ORTEGA Manuel	26/02/2007

Council of the European Union

Council configuration	Meeting	Date
Agriculture and Fisheries	2904	18/11/2008
General Affairs	2848	10/03/2008
Agriculture and Fisheries	2841	17/12/2007
Employment, Social Policy, Health and Consumer Affairs	2803	30/05/2007

European Commission

Commission DG	Commissioner
Health and Food Safety	VASSILIOU Androulla

Key events

28/07/2006	Legislative proposal published	COM(2006)0428	Summary
05/09/2006	Committee referral announced in Parliament, 1st reading		
11/04/2007	Vote in committee, 1st reading		Summary
20/04/2007	Committee report tabled for plenary, 1st reading	A6-0154/2007	
30/05/2007	Debate in Council	2803	Summary
09/07/2007	Debate in Parliament		
10/07/2007	Results of vote in Parliament		
10/07/2007	Decision by Parliament, 1st reading	T6-0321/2007	Summary
24/10/2007	Modified legislative proposal published	COM(2007)0673	Summary
10/03/2008	Council position published	16675/2/2007	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	A6-0180/2008	
07/07/2008	Debate in Parliament		
08/07/2008	Decision by Parliament, 2nd reading	T6-0330/2008	Summary
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	2006/0145(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
	Repealing Directive 95/2/EC 1992/0424(COD) Repealing Decision No 292/97/EC 1995/0085(COD)
Legal basis	EC Treaty (after Amsterdam) EC 095
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/6/58917

Documentation gateway

Legislative proposal		COM(2006)0428	28/07/2006	EC	Summary

Document attached to the procedure		SEC(2006)1040	28/07/2006	EC	
Document attached to the procedure		SEC(2006)1041	28/07/2006	EC	
Committee draft report		PE384.474	12/02/2007	EP	
Amendments tabled in committee		PE386.367	09/03/2007	EP	
Committee opinion	JURI	PE386.576	22/03/2007	EP	
Committee report tabled for plenary, 1st reading/single reading		A6-0154/2007	20/04/2007	EP	
Text adopted by Parliament, 1st reading/single reading		T6-0321/2007	10/07/2007	EP	Summary
Commission response to text adopted in plenary		SP(2007)4170	29/08/2007	EC	
Modified legislative proposal		COM(2007)0673	24/10/2007	EC	Summary
Council position		16675/2/2007	10/03/2008	CSL	Summary
Commission communication on Council's position		COM(2008)0143	11/03/2008	EC	Summary
Committee draft report		PE404.469	13/03/2008	EP	
Amendments tabled in committee		PE404.734	09/04/2008	EP	
Committee recommendation tabled for plenary, 2nd reading		A6-0180/2008	13/05/2008	EP	
Text adopted by Parliament, 2nd reading		T6-0330/2008	08/07/2008	EP	Summary
Commission opinion on Parliament's position at 2nd reading		COM(2008)0608	17/10/2008	EC	Summary
Draft final act		03660/2008/LEX	16/12/2008	CSL	

Additional information

National parliaments	IPEX
European Commission	EUR-Lex

Final act

Regulation 2008/1333
OJ L 354 31.12.2008, p. 0016 Summary

Food additives

PURPOSE: to regulate food additives.

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

CONTENT: currently, food additives are regulated through four co-decision framework Directives; three specific Directives and three Commission Directives. For the sake of improved efficiency and greater simplicity, the Commission is proposing to repeal the existing legislative acts and replace them with a new single Regulation in which all existing food additives are brought under one umbrella. The stated objectives of this proposed Regulation are:

- to simplify food additive legislation by creating a single instrument for procedures and approvals;
- to confer the right of updating and implementing the Community list of authorised food additives to the Commission;
- to consult the European Food Safety Authority (EFSA) for the safety evaluation of food additives;

- to set up a re-evaluation programme for existing food additives; and
- to require authorisation from additives containing GMOs, as defined by Regulation 1829/2003.

This proposal is being forwarded to the Parliament and Council alongside three related proposed Regulations on:

- Establishing a common authorisation procedure for food additives, food enzymes and food flavourings. (For a summary refer to COD/2006/0143)
- Food enzymes; (For a summary refer to COD/2006/0144)
- Certain food ingredients with flavouring properties for use in and on food. (For a summary refer to COD/2006/0147).

The Commission notes that food additives are fully harmonised in the EU albeit through a number of legislative acts. This Regulation, however, would combine current provisions into a single instrument and thereby facilitate the use of food additives across the EU. In a further development, the Commission is proposing to replace the current practice of using the ?co-decision? procedure for the authorisation of an additive (which is lengthy and cumbersome) with the ?regulatory? procedure. Such a move would speed up considerably the approval procedure for food additives.

In summary, the provisions proposed would state that food additives used in foods, in food additives and in food enzymes would be subject to safety evaluation and approval via a Community-approved positive list. Their use in food will be evaluated according to their safety, technological need, benefit to the consumer and that the consumer is not being misled. All applications for the approval of new food additives will be directed to the EFSA, which will be responsible for carrying out the safety evaluations. The inclusion of a food additive to the list will be considered by the Commission on the basis of the EFSA opinion. The more general criteria such as technological need and consumer interest will be examined by the Standing Committee on the Food Chain and Animal Health (SCFSAH). Final inclusion on the list will be done by the Commission.

A food additive which consists, contains, or is produced from a genetically modified organism, should be authorised in accordance with Regulation 1829/2003/EC on genetically modified food and feed ? prior to its inclusion in the positive list established by the new Regulation.

In other provisions, the Regulation lays down the general rules on placing food additives on the market, the labelling of additives sold to the manufacturer or directly to the consumer and the need to keep the Commission abreast of any new information pertaining to food additives. Implementation of the measures proposed in the Regulation will be adopted by the Commission in accordance with the regulatory procedure. This consists of including the use of a food additive and laying down he conditions of use in the positive list as well as laying down criteria on origin and purity. Given that these are matters of high technicality, and given that they are adopted on the basis of commonly agreed principles, the Commission argues that it should be entrusted with these tasks.

Lastly, food additives listed under current legislation will be entered into Annex II of this proposal following a review by the SCFCAH. Until its review has been notified the existing legislation will continue to apply. In addition, the Authority will be required to carry out a risk assessment on all currently approved food additives.

The proposal has some implication for the Community budget. The Commission is seeking funding for the development of a database capable of gathering and storing all Community legislation on food additives; undertaking studies on the preparation and development of food additive legislation and to undertake studies on harmonising procedures, decision-making criteria and data requirements and how to facilitate work-sharing between the Member States. This kind of support expenditure is covered by Regulation 882/2004 on official feed and food controls and is in line with its 2007-2013 implementation period.

Food additives

In adopting the report drafted by Ms Asa WESTLUND (PES, SE), the Committee on the Environment, Public Health and Food Safety amended in first reading the proposal for a Regulation of the European Parliament and of the Council on food additives.

The Commission has proposed that, in future, decisions on the authorisation of food additives should be taken by way of the comitology procedure. While the Committee can see that this might have advantages, this would only be in the event that the considerations which the European Parliament has often raised over the years are clearly reflected in the new Regulation on food additives and the new Regulation on a common authorisation procedure for food additives, food enzymes and food flavourings. These considerations mainly relate to the environment, public health and allergy sufferers.

The main amendments were as follows:

- the legal base: in view of the provisions of the proposal and its recitals, in particular, the Committee considered that that the aims of protecting human health and the establishment and functioning of the internal market are indissolubly linked with each other without one being secondary and indirect in respect of the other. The proposal's aims connected with the protection of human health and the functioning of the internal market appear to be equally balanced. It is considered, therefore, that the legal basis should be both Article 95 and Article 175 of the EC Treaty. This viewpoint also received the unanimous support of the Legal Affairs Committee;

- environmental concerns: in accordance with the Cardiff Process, environmental aspects must be integrated into all EU legislation. This is particularly relevant in this legislation as what a person eats does not stay in the human body but is dispersed into the natural environment and becomes part of the natural cycle. Even if a substance does not entail any health risk to the person consuming the product which contains the substance, there may be negative effects on the environment and public health at subsequent stages, which should be taken into account when deciding to grant authorisation or not. The use of antibiotics in food and its implications for the development of resistance to antibiotics is one example of what may have damaging effects on public health. The committee therefore specifically includes environmental protection in the aims of the regulation.

- scope: MEPs believe that this regulation should refer to the whole food additive package, as this will avoid the need for subsequent corrections. For this reason, they introduced an amendment to ensure that food enzymes, flavourings and certain food ingredients with flavouring properties should be covered in this regulation. In addition, an amendment whereby foodstuffs which contain additives that do not comply with this Regulation shall not be placed on the market was introduced by the Committee. This makes explicit what is already implicit in the proposal but which is not stated clearly within the Commission?s original text. Furthermore, whereas the Commission proposed that

substances used for the protection of plants and plant products in conformity with Community rules relating to plant health should be excluded from the regulation?s scope, the Committee considered that post-harvest pesticides like Methylcyclopropene (1-MCP) used for conserving fruit and vegetables (mainly apples) should fall within its scope. Lastly, in adding a paragraph to Article 2, MEPs sought to ensure consistency with the proposal for a Regulation on Food Enzymes and to harmonize regulations in the Authorisation package by excluding microbial cultures producing food additives from the scope of the draft regulation.

- greater legal certainty: Members of the Committee also introduced amendments to ensure greater legal clarity regarding definitions such as ?reduced sugar? foods, ?sugars?, ?table-top sweeteners? and quantum satis. Furthermore, in the interests of the clearer administration of justice and with a view to avoiding legal uncertainties in advance, an explicit ban is introduced on the use of a food additive and/or food containing such a food additive being placed on the market and/or in circulation if the use of this food additive does not comply with the requirements of this Regulation ..

- transparency and review: authorisations for use of additives must be subject to rolling review. In the committee?s view, all current authorisations should be reviewed on the basis of the new criteria before they are transferred to the new Community list. Thereafter, the rolling review of authorisations should continue by way of a transparent procedure in accordance with an evaluation programme to be adopted by comitology procedure. The evaluation programme should be based on a priority system whereby additives are ranked according to the urgency of reviewing their use. This priority ranking should be drawn up by means of an evaluation programme so that it is clear to all parties involved. The evaluation programme must not, however, prevent the Commission and/or the EFSA from taking initiatives to review certain authorisations more promptly. To increase the openness and transparency of the authorisation of additives by publicly stating how the authorisation meets the conditions laid down in the proposal, MEPs introduced an amendment to ensure that with the exception of proprietary knowledge and information which it is appropriate to keep confidential, the approval of a food additive refers explicitly and transparently to the consideration given to the criteria laid down in the regulation, and explains the basis for the final decision.

Consumer interests:

- because consumers are sometimes misled by the use of additives despite the fact that one of the criteria for authorisation under previous legislation was that consumers must not be misled, the Committee introduced amendments to ensure, for example, that consumers are not misled into believing that a product contains a certain fruit through the use of a particular colour for the product;
- likewise, Members sought to ensure that the use of flavour enhancers would not be authorised as a means for reducing the amount of (more expensive) spices in a processed food;
- because some additives interact to create a new compound, which has different properties and implications for human health or the environment than its two component substances, the Committee has introduced an amendment to provide for the case that if this produces a harmful or toxic effect, the combination of food additives should be noted in the Annexes of the Community list;
- as little is known about the health risks of nanotechnology, it is not certain that the limit value for traditional use of an additive and the limit value for nanoparticles of an additive should be the same. The Committee introduced an amendment to ensure that when the use of nanotechnology is authorised, separate limit values for that purpose shall be laid down;
- the Committee makes provision for food additives produced from or by genetically modified organisms or micro-organisms to be clearly labelled as such in order to guarantee the freedom of choice of consumers;
- as Azo-Dyes can provoke allergenic reactions, members want a clear warning to be required by the regulation.

- codecision: The Committee proposes codecision as the legal procedure for the establishment of the positive lists and the reevaluation of approved food additives.

- comitology: a series of amendments were approved to align the text with the provisions of the new comitology decisions.

Lastly, the Committee?s amendments provide that food additives which are on the market on the date of entry into force of this Regulation, but have not been reviewed and received a positive opinion from the Scientific Committee on Foods or the European Food Safety Authority, shall be subject to a new risk assessment carried out by the Authority. These additives will be allowed to remain on the market until the new risk assessment has been carried out by the Authority.

Food additives

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 additives

The European Parliament adopted a resolution drafted by Asa WESTLUND (PES, SE), and made some amendments to the Commission?s proposal. It considered that the environmental impact of food additives must not be overlooked, that they should only be used if they bring benefits to consumers and they must not mislead consumers as to specific qualities, for example, the freshness or naturalness of a product. There should be separate limit values for nanotechnologies, and labels should state whether an additive has been produced from GMOs and whether it contains azo-dyes. All additives already on the market will gradually be re-evaluated. The principal amendments were as follows:

- when updating and amending the Community list of food additives to be established under the Regulation, the regulatory procedure with scrutiny will apply;

- food additives must not have negative effects on the environment;

- a new clause states that foodstuffs which contain additives that do not comply with the Regulation shall not be placed on the market;

- microbial cultures producing food additives are excluded from the scope of the draft regulation;

- new definitions were inserted for 'food reduced in sugars' and "quantum satis?;

- food additives must be technologically necessary in terms of benefits to consumers;

- the nature, substance or quality of the food must not be changed in such a way as to mislead the consumer. Misleading the consumer includes, but is not limited to, issues related to freshness and quality of the ingredients used, naturalness of a product and fruit and vegetable content;

- with the exception of proprietary knowledge and information which it is appropriate to keep confidential, the approval of a food additive must refer explicitly and transparently to the consideration given to prescribed criteria laid down in the legislation, and must explain the basis for the final decision;

- there must be no risk of the additive misleading consumers into believing that the food contains ingredients other than those actually present;

- the Community list should be complete in the information relating to the additives in the list with the name of the additive, additive group, and E number;

- if the use of nanotechnology is authorised, separate limit values for that purpose shall be laid down in accordance with the terms of the regulation;

- food additives produced from or by genetically modified organisms or micro-organisms should be clearly labelled as such in order to guarantee the freedom of choice of consumers;

- the labelling of food additives containing azo-dyes shall bear the warning "azo-dyes may provoke allergenic effects";

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

- by way of derogation from the labelling and information requirements in the draft regulation, for bulk deliveries all of the information may appear on the accompanying documents which are to be supplied with or prior to the delivery;

- food additives which were on the market at the date of entry into force of the Regulation, but have not been reviewed and received a positive opinion from the Scientific Committee for Food or the EFSA (the Authority), shall be subject to a new risk assessment carried out by the Authority. These additives will be allowed to remain on the market until the new risk assessment is carried out. The Authority's risk assessment will form part of the review to be carried out by the Commission, assisted by the Committee, of all food additives which were approved prior to the entry into force of the Regulation. This review will be conducted on the basis of the conditions of authorisation laid down in the Regulation, and on the basis of an assessment of intake and risk management. All food additives that are to continue to be authorised in the Community will be transferred to the Community lists in Annexes II and III. Annex III will be completed with the other food additives used in food additives and enzymes and their conditions of use in accordance with the regulation establishing a common authorisation procedure for food additives, food enzymes and food flavourings. (Please refer to COD/2006/0143.) To allow a suitable transition period, the provisions in Annex III, other than the provisions concerning carriers for food additives, will not apply until 01/01/2011. The review will be conducted on the basis of an evaluation programme which will be adopted, after consultation of the Authority, within one year after the date of entry into force of the Regulation, in accordance with the regulatory procedure with scrutiny;

- after the evaluation has been carried out, and after consultation of the Authority, a new evaluation programme will be adopted for authorisations pursuant to the Regulation, and in accordance with the regulatory procedure with scrutiny. Food additives and uses which are no longer current shall be removed from the Annexes when the authorisationis reviewed.

Food additives

The Commission has amended its initial proposal taking account of Parliamentary amendments tabled at first reading. With regard to the original proposal, the European Parliament adopted 59 amendments of which many the Commission has accepted many in whole, or in part, subject to some rewording. 20 amendments, however, were not accepted.

A number of the proposed amendments seek to improve the proposal from a technical and editorial point of view. These have largely been taken over by the Commission.

Scope: The Commission has decided not to include ?plant protection products for post harvest treatments? within the scope of the Regulation given that this is already subject to separate Community legislation. However, should a substance or substances used for post harvest treatment not fall under the plant protection product definition it could be considered a food additive ? if it has a ?preservative? effect. Further the Commission has decided not to accept that microbial cultures should be excluded from the Regulation, as Parliament had proposed. Some cultures are added to foods near the end of their manufacture for an intended preservation effect and should, therefore, be considered food additives. Based on this reasoning they should not be excluded from food additives legislation.

Comitology: The Commission endorses Parliamentary proposals that the Regulation?s implementary powers should be based on the « regulatory procedure with scrutiny » as set out in Decision 2006/512/EC. There is one exception to this rule however. In one of its amendments, Parliament proposes that the « regulatory procedure with scrutiny » should be used for deciding whether or not a given substance falls within the scope of the Regulation. The application of this provision is an implementation of the rules contained in the basic act (« food additive » definition) and should therefore not fall within the new regulatory procedure with scrutiny. Consequently, the Commission?s amended initial proposal specifies that under such conditions the normal ?regulatory procedure? will continue to apply.

Prohibition of non-compliant food additives: The Commission endorses Parliamentary proposals to clarify that a food additive or a food that does not comply with the proposed Regulation should not be placed on the market.

Criteria for authorisation: The Commission has decided to amend its initial proposal in order to clarify what is meant by misleading the consumer (as suggested by Parliament). Suggestions that the precautionary principle should apply have, however, been rejected on the grounds that this principle is covered by the ?General Food Law? Regulation. A Parliamentary amendment to link ?technological need? for a food additive with ?consumer benefit? has been similarly rejected on the grounds that a food additive can be beneficial for manufacturers. For example, when a food additive reduces wastage in a production process.

Environmental aspects: On the matter of linking ?environmental impact? as a general condition for authorising food additives the Commission has decided not to accept the amendment but it has agreed to reinforce the environmental aspects of the text.

Allergenicity of food: Allergies and food additives are already regulated by labelling provisions set out in Directive 2000/13/EC and as such the Commission will not accept an outright restriction on the use of food additives which may be allergenic. The allergenicity of a food additive can, of course, be considered a legitimate factor during the authorisation process. This process is, therefore, emphasised in recital 7 of the proposed Regulation.

Sweeteners: The Commission has decided not to accept Parliamentary amendments concerning sweeteners. The current criteria for the use of sweeteners restrict their use to foods which are energy reduced or which contain no added sugar. This ensures that consumer benefit from the use of such sweeteners.

Colours: Parliamentary amendments on colourings have been rejected by the Commission on the grounds that they do not mislead the consumer and that labelling provisions are stringent enough.

Community lists of food additives: The Commission has decided not to accept amendments that would include, in the Community list, a reference to other food additives which may not be used in combination with the food additive.

GM food and feed: The Commission has agreed to adopt amendments, which seek to clarify that two procedures for approving GMO food additives can run simultaneously in accordance with good administrative practices.

Azo dyes: The Commission reiterates that allergens are addressed horizontally under Directive 2000/13/EC and that, as a result, the issue of allergen labelling should be addressed under that legislation.

Nanoscale food additives: Amendments on introducing separate limit values for nanoscale food additives have not been accepted by the Commission since specific restrictions could already be allocated under the conditions of use if these are deemed necessary. Given the importance of this issue, however, the revised text reiterates and clarifies that nanoscale additives will need to be evaluated by the EFSA before they can be approved. Further, the amended Commission proposal includes a new Article 11 introducing requirements for food additives already included on the Community list which are prepared by production methods or staring materials significantly different from those included in the risk assessment of the Authority.

Reviews and evaluations: Regarding Parliamentary proposals to link the timing of reviewing all existing food additive authorisations with that of an EFSA re-evaluation of the safety of all current permitted food additives, the Commission has opted not to accept this proposal. The timing of both reviews will be different hence the Commission considers it unnecessary to bind the two reviews together. On the matter of moving from Annex II to Annex III ?food additives in flavourings? the Commission has accepted this amendment and the proposal has been amended accordingly.

Rolling re-evaluation programme: Parliament had proposed that a requirement should be introduced for a rolling re-evaluation programme. The Commission, however, has rejected this amendment on the grounds that food additives are subject to continuous observation once they have been authorised and are re-evaluated whenever new scientific data becomes available. A regular review is, as a result, not necessary and seen as an added administrative burden for both the EFSA and the Commission.

Transitional provisions: The Commission has accepted a Parliamentary amendment whereby food additives, which are legally labelled, will be allowed to remain on the market until their date of minimum durability.

Food additives

The Council has introduced a number of modification to the text of the initial proposal with many of these modification based on amendments proposed by the European Parliament. Some of the Parliamentary amendments were introduced by Council on its own initiative. Of the 59 amendments proposed by Parliament, the Council has decided to adopt either in principle or in full, 33 amendments.

In summary, the modifications made by Council are as follows:

Misleading the consumer: the Council has included references to ?misleading the consumer? in both recital 7 and Article 6.

Environmental protection: the Council has modified the proposal so that prior to an authorisation being granted, scientific evaluators should take any environmental impacts into consideration. Environmental protection is also listed as one of the Regulation?s objectives.

Food intolerance or allergies: the Council recognises that the use and maximum levels of food additives should take account of exposure to special groups of consumers and those with allergies in particular.

Regulatory comitology procedure with scrutiny: the Regulation has been adapted so that in cases where measures are adopted that supplement the Regulation, the regulatory procedure with scrutiny will apply. In order to improve the efficiency of the Regulation?s provisions the Council decided to use the regulatory procedure with scrutiny with curtailed time limits when establishing the Community list of additives. This will also apply to transitional measures.

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.

Authorisation of additives falling within the scope of Regulation (EC) No 18 29/2003 on genetically modified food and feed: the Council agrees that two authorisation procedures can be carried out simultaneously, albeit that final authorisation will be subject to the food additives Regulation. Some drafting changes to the text have been made in order to make these provisions compatible with Regulation (EC) No 1829/2003.

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

Labelling: the common position streamlines labelling provisions in a bid to harmonise them with provisions already laid down by Directive 2000/13/EC. A distinction is drawn between ?business to business? labelling and the labelling of products intended for the final consumer. Although, the structure of the Chapter on Labelling is different to that proposed by Parliament, the underlying principles, nevertheless, remain the same.

Nanotechnology: in line with amendments proposed by Parliament, the Council agrees that, in cases where a food additive has been produced by methods significantly different from those included in previous risk assessments, then, a new evaluation will be necessary.

Parliamentary amendments not incorporated in the common position include, inter alia:

Precautionary principle: given that this principle already applies to general food law, the Council has decided there is no specific need to refer to it in the proposed Regulation. Further, and taking account of the risk analysis 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.

Food additives not to be used with other food additives: the Regulation already stipulates that the use of food additives has to be listed in the Community list, thus it is superfluous to repeat this.

Re-evaluation programme to review authorisations: the Council is of the view that strict review criteria already exist in the proposed Regulation. A system is already being proposed for the continuous observation and re-evaluation of food additives that take account of changing circumstances. An additional review would represent an unnecessary administrative burden for producers, users, the EFSA, the Commission and the Member States.

Review of existing authorisations: the Council is of the view that additives that have already been authorised can be transferred on the list of authorised additives once the safety review has take place. The Council does not believe that it is necessary for the EFSA to conduct a second review.

Scope: the common position does not extend the scope of the proposed Regulation to include ?plant protection products used for post-harvest treatment? given that they are already subject to Directive 91/414/EEC. On the other hand, the Council is of the view that ?microbial cultures? should be included in the scope of the Regulation given that some cultures are added to foods toward the end of their manufacture for preservation purposes. Similarly, given that ?blood proteins? are already listed as a food additive under existing Community law they too should be included in the scope of the proposed Regulation.

Decision submitted to the regulatory comitology procedure: decisions on whether or not a given substance should fall within the scope of the Regulation are of an interpretive nature and as a result do not fall under the regulatory comitology procedure with scrutiny.

Definitions: the Council decided not to include an ?additional technological? effect in Article 3 on the grounds that it is too broad and may exclude substances used as food additives.

Food reduced in sugars: The Council decided that introducing the concept of ?food reduced in sugars? could result in an increase of products in which sweeteners may be used, leading to a possible increase in the consumption of such additives.

Consumer benefits: an amendment proposing that one of the conditions for including a good additive on the Community list should refer to a ?reasonable technological need? in terms of benefiting the consumer. However, the proposed Regulation already stipulates that an additive needs to have certain benefits and advantage for the consumer ? repeating this requirement would, therefore, be superfluous.

Labelling GMOs: food additives remain subject to the labelling provisions as defined in Directive 2000/13/EC on the approximation of the laws relating to labelling, presentation and advertising foodstuffs, as well as Regulation (EC) No 1829/2003 on genetically modified food and feed. Any amendments that could potentially interfere with the scope of the horizontal Regulations in force have not been accepted by Council.

To conclude, the Council is of the view that the common position is both balanced and objective as well as having taken account of Parliamentary suggestions.

Food additives

The Commission supports the common position adopted by the Council given that it is line with the main aims of the Commission?s initial proposal as well as taking account of several amendments proposed by Parliament at first reading.

Parliamentary amendments at first reading accepted by the Commission and Council:

Most of the 39 amendments proposed by Parliament have been incorporated into the Council?s common position either in part, in full or in principle.

For example, the common position includes amendments concerning environmental protection. Thus, in cases where there is clear evidence that the production of a certain food additive may have an environmental impact, this should be taken into account when granting authorisation for the food additive in question. The Council proposes that the definition of quantum satis should be included in Article 3 and as a result has made considerable changes to Article 11. Such changes reflect, by and large, Parliamentary proposal and the Commission can accept them.

A new Article in the common position (Article 5) clarifies that no person will place a food additive or a food in which a food additive is used on the market, if its use does not comply with the Regulation. This too was a clarification requested by Parliament.

Regarding the interplay between the proposed Regulation and EU GMO provisions, the EP clarified that the evaluation and authorisation procedures under these two Regulations should run simultaneously. This important principle has been adopted by the Council in its common position.

Some of the recitals have been modified by the common position in order to introduce the regulatory procedure with scrutiny and to align the proposed Regulation with Council Decision 2006/512/EC laying down procedures for the exercise of implementing powers conferred on the Commission. These changes are in line with some of the EP?s amendments. The common position, unlike Parliamentary amendments, does however include the curtailment of time periods in some cases. This aspect was not reflected in the Commission?s amended proposal.

Further, the common position includes a provision in Article 28 clarifying the transfer of current authorisation for food additives into the new annexes. This too reflects suggestions put forward by Parliament at first reading.

New provisions introduced in the common position and accepted by the Commission:

In summary these include:

- obliging manufacturers to make information available on sweeteners used in table top sweeteners. This would provide useful information to the consumer and to the Member States;
- the common position has removed a requirement that food additives should, at all times, comply with the specific purity criteria (specification) which have been set. The common position now states simply that food additives must comply with the ?specification?;
- a new recital has been introduced in order to describe in greater detail the principle of ?carry over?;
- on the matter of labelling, the common position reflects, by and large, similar provisions to those proposed by Parliament with regard to the date of minimum durability/shelf life and derogations for food additives delivered by bulk transport such as a tanker. In addition the Council has gone further in simplifying labelling provisions for food additives sold directly to the final consumer;
- the Council has made some adjustments to recital 13 and Article 24 in order to clarify that a new nanoscale form of a food additive would be a significantly different production method and, as a result, would require a new safety assessment;
- the Council has proposed an amendment that allows the current Directive to be amended by comitology during the interim period so that those food additives in the pipeline, which have already received a positive opinion from the European Food Safety Authority, may be authorised. As a result the common position includes a new Article 29 and changes have been made to Article 33;
- the common position includes a modification that clarifies the meaning of ?extending shelf life through the replacement of sugars?. The Commission has decided to accept the new wording set out in the common position;
- in order to improve enforcement, the Council has decided to establish marketed food levels rather than to have a general rule that the levels of food additives should apply to ready to eat food. For foods that have been reconstituted or diluted, levels should be established accordingly;
- the common position includes a new provision that reflects the need, created by changes to the labelling provisions, that a transitional period is provided for products which no longer comply with the new rules.

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

Food additives

The Committee on the Environment, Public Health and Food Safety unanimously adopted a report drafted by Åsa WESTLUND (PES, SE) recommending some amendments to the Council's common position for adopting a regulation of the European Parliament and of the Council on food additives. It reinserted several amendments that had not been taken up by the Council in its common position. The main amendments are as follows:

Scope: post-harvest pesticides like Methylcyclopropene (1-MCP) used for conserving fruit and vegetables (mainly apples) shall fall within the scope of the regulation.

Environmental factors: a food additive may be included in the Community lists only if it meets certain ns and, other legitimate factors, including environmental factors.

Benefit to the consumer: there must be a reasonable technological need, in terms of benefits to the consumer, that cannot be achieved by other economically and technologically practicable means. There must, however, be no risk of the additive misleading the consumer into believing that the food contains ingredients other than those actually present.

Nanotechnology:a new clause states that when a food additive is already included in a Community list and there is a significant change in the production methods or the starting materials, or a change in particle size, for example through nanotechnology, the food additive prepared by those new methods or materials shall be considered as a different additive, and a new entry in the Community lists or change in the specifications shall be required before it can be placed on the market. This amendment aims to facilitate a compromise with the Council on nanotechnology.

Azo-dyes: the labelling of food additives containing azo-dyes shall display the warning "azo-dyes may provoke allergenic effects and hyperactivity in children".

Enzymes: the Regulation shall not apply to food enzymes falling within the scope of the Regulation on enzymes with effect from the date of application of the Community list of food enzymes in accordance with Article 17 of that Regulation. The committee stated that it was necessary to prevent a temporary lowering of controls on currently unauthorised enzymes which have an additive function. Without this amendment such enzymes will not require authorisation until adoption of the Community list of enzymes.

Lastly, any GM product used for the production of additives already approved and included in the list of approved additives must also be approved in accordance with Regulation 1829/2003.

Food additives

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 additives. The recommendation for second reading (under the codecision procedure) had been tabled for consideration in plenary by Asa WESTLUND (PES, SE) 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 2nd reading of the codecision procedure - were as follows:

Consumer protection: Parliament stressed that the purpose of the Regulation is to ensure the effective functioning of the internal market whilst ensuring a high level of protection of human health and a high level of consumer protection, including protection of consumer interests and fair practices in food trade;

Enzymes: the Regulation shall not apply to food enzymes falling within the scope of the Regulation on food enzymes, with effect from the date of adoption of the Community list of food enzymes in accordance with Article 17 of that Regulation;

Environmental factors: a food additive may be included in the Community lists only if it meets certain conditions and, other legitimate factors, including environmental factors.

Nanotechnology: a new clause states that when a food additive is already included in a Community list and there is a significant change in the production methods or the starting materials, or a change in particle size, for example through nanotechnology, the food additive prepared by those new methods or materials shall be considered as a different additive, and a new entry in the Community lists or change in the specifications shall be required before it can be placed on the market.

Regulation (EC) No 1829/2003: where a food additive 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 additive complies with the specifications established under this Regulation.

Labelling requirement for foods containing certain food colours: the labelling of food containing the food colours listed in Annex V to this Regulation shall include the additional information set out in that Annex. The new Annex V lists the food colours referred to for which the labelling of foods shall include additional information. They include Sunset yellow (E 110), Quinoline yellow (E 104), Carmoisine (E 122), Allura red (E 129) Tartrazine (E 102) and Ponceau 4R (E 124). These must be accompanied by the words ?may have an adverse effect on activity and attention in children.?The list excludes those foods where the colour(s) has been used for the purposes of health or other marking on meat products or for stamping or decorative colouring on eggshells. Where necessary as a result of scientific progress or technical development, Annex V shall be amended by measures in accordance with the regulatory procedure with scrutiny. Foods placed on the market or labelled before 18 months after the date of entry into force of the Regulation which do not comply with this provision may be marketed until their date of minimum durability or use-by-date.

Food additives

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. The amendments are mainly of technical nature and are generally in line with and strengthen the key principles of the initial proposal.

Of particular note are the amendments which will require labelling of the possible adverse effect on children's behaviour which has been associated with certain food colours.

Other amendments concern the clarification of the interplay between the proposed Regulation on food additives and Regulation (EC) No 1829/2003 on genetically modified food and feed and also clarifying that food additives which are produced using different production processes or with different starting materials require a new safety evaluation. 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 additives

PURPOSE: to regulate food additives.

LEGISLATIVE ACT: Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives.

CONTENT: the Council adopted a Regulation on food additives following agreement reached with the Parliament at second reading. It lays down rules on food additives used in foods with a view to ensuring the effective functioning of the internal market whilst ensuring a high level of protection of human health and a high level of consumer protection, including the protection of consumer interests and fair practices in food trade, taking into account, where appropriate, the protection of the environment.

The approval of food additives should also take into account other factors relevant to the matter under consideration including societal, economic, traditional, ethical and environmental factors, the precautionary principle and the feasibility of controls.

The objectives of this Regulation are:

- to simplify food additive legislation by creating a single instrument for principles, procedures and approvals;
- to confer the implementing powers on the Commission to update the Community list of authorised food additives;
- to consult the European Food Safety Authority (EFSA) for the safety evaluation of food additives;
- to set up a re-evaluation programme for existing food additives;
- to require the authorisation of food additives that consist of, contain or are produced from genetically modified organisms under Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed.

The Regulation provides for:

- Community lists of approved food additives as set out in Annexes II and III;
- conditions of use of food additives in foods, including in food additives and in food enzymes as covered by Regulation (EC) No 1332/2008 on food enzymes, and in food flavourings as covered by Regulation (EC) No 1334/2008;
- rules on the labelling of food additives sold as such.

To be included in the Community lists in Annexes II and III a food additive must have advantages and benefits for the consumer and therefore serve one or more of the following purposes: (i) preserving the nutritional quality of the food; (ii) providing necessary ingredients or constituents for foods manufactured for groups of consumers with special dietary needs; (iii) enhancing the keeping quality or stability of a food or improving its organoleptic properties.

There are specific conditions for sweeteners and colours.

Food additives shall not be used in foods for infants and young children as referred to in Directive 89/398/EEC, including dietary foods for infants and young children for special medical purposes, except where specifically provided for in Annex II to this Regulation.

In accordance with Parliament?s wishes, the Regulation stipulates that additional information shall be included on the labelling of foods containing one or more of the following food colours - Sunset yellow (E 110); Quinoline yellow (E 104); Carmoisine (E 122); Allura red (E 129); Tartrazine (E 102); Ponceau 4R (E 124). The label should include the name or E number of the colour(s)? and that it ?may have an adverse effect on activity and attention in children?.

When a food additive 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 additive complies with the specifications established under this Regulation.

Food additives which were permitted before 20 January 2009 shall be subject to a new risk assessment carried out by the EFSA, and an evaluation programme for those additives shall be adopted by 20 January 2010.

The text contains provisions which will require labelling of the possible adverse effect on children's behaviour which has been associated with certain food colours.

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, food enzymes and flavourings. 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.

ENTRY INTO FORCE: 20/01/2009.

APPLICATION: from 20/01/ 2010. However, there are transitional arrangements for certain parts of the Regulation.