

Basic information	
<p>2006/0143(COD)</p> <p>COD - Ordinary legislative procedure (ex-codecision procedure) Regulation</p>	Procedure completed
<p>Food safety, human health protection: common authorisation procedure for food additives, food enzymes and food flavourings</p> <p>Amended by 2018/0088(COD)</p> <p>Subject</p> <p>3.10.10 Foodstuffs, foodstuffs legislation 4.60.04.04 Food safety</p>	

Key players			
European Parliament	Committee responsible	Rapporteur	Appointed
	ENVI Environment, Public Health and Food Safety	WESTLUND Åsa (PSE)	14/09/2006
	Former committee responsible	Former rapporteur	Appointed
	ENVI Environment, Public Health and Food Safety	WESTLUND Åsa (PSE)	14/09/2006
	Former committee for opinion	Former rapporteur for opinion	Appointed
	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	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	2904	2008-11-12
	Agriculture and Fisheries	2841	2007-12-17
European Commission	Commission DG	Commissioner	
	Health and Food Safety	VASSILIOU Androulla	

Key events			
Date	Event	Reference	Summary
28/07/2006	Legislative proposal published	COM(2006)0423 	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	A6-0153/2007	
30/05/2007	Debate in Council		Summary
09/07/2007	Debate in Parliament		
10/07/2007	Decision by Parliament, 1st reading	T6-0320/2007	Summary
10/07/2007	Results of vote in Parliament		
24/10/2007	Modified legislative proposal published	COM(2007)0672 	Summary
10/03/2008	Council position published	16673/2/2007	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	A6-0179/2008	
07/07/2008	Debate in Parliament		
08/07/2008	Decision by Parliament, 2nd reading	T6-0329/2008	Summary
08/07/2008	Results of vote in Parliament		
12/11/2008	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	2006/0143(COD)

Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
Amendments and repeals	Amended by 2018/0088(COD)
Legal basis	EC Treaty (after Amsterdam) EC 095
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/6/58915

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee draft report		PE384.475	07/02/2007	
Amendments tabled in committee		PE386.368	15/03/2007	
Committee opinion	JURI	PE386.571	22/03/2007	
Committee report tabled for plenary, 1st reading/single reading		A6-0153/2007	20/04/2007	
Text adopted by Parliament, 1st reading/single reading		T6-0320/2007	10/07/2007	Summary
Committee draft report		PE404.468	13/03/2008	
Amendments tabled in committee		PE404.695	09/04/2008	
Committee recommendation tabled for plenary, 2nd reading		A6-0179/2008	13/05/2008	
Text adopted by Parliament, 2nd reading		T6-0329/2008	08/07/2008	Summary

Council of the EU

Document type	Reference	Date	Summary
Council position	16673/2/2007	10/03/2008	Summary
Draft final act	03658/2008/LEX	16/12/2008	

European Commission

Document type	Reference	Date	Summary
Legislative proposal	COM(2006)0423 	28/07/2006	Summary
Commission response to text adopted in plenary	SP(2007)4170	29/08/2007	
Modified legislative proposal	COM(2007)0672 	24/10/2007	Summary
Commission communication on Council's position	COM(2008)0145 	11/03/2008	Summary
Commission opinion on Parliament's position at 2nd reading	COM(2008)0605 	17/10/2008	Summary

Additional information

Source	Document	Date
National parliaments	IPEX	
European Commission	EUR-Lex	

Final act

[Regulation 2008/1331](#)
[OJ L 354 31.12.2008, p. 0001](#)

[Summary](#)

Food safety, human health protection: common authorisation procedure for food additives, food enzymes and food flavourings

2006/0143(COD) - 24/10/2007 - Modified legislative proposal

The European Parliament adopted 31 amendments in total with regard to the Commission's original proposal. The Commission has accepted most of the amendments, either in whole or in part and subject to some rewording. Four were rejected.

Technical/editorial amendments: The majority of amendments (in this case 21) seek to improve the proposal from a technical and editorial point of view. These amendments have largely been taken over by the Commission.

Transparency: Most amendments that seek to strengthen the transparency of the proposal have been accepted by the Commission given that information provisions form an integral part of the initial proposal. One amendment, however, that would require all application files to become available to stakeholders has been rejected. The Commission intends to make public a list of all request for authorisation and information. The routine publication of the full application files is not, though, considered acceptable.

Five year data protection with individual authorisation: Parliamentary proposals to provide for a five year period of data protection has not been taken over in the amended proposal. Such a provisions would change radically the present system for food additives. It would also result in a duplication of regulatory procedures, a compilation of systems of control and increased administrative procedures. Such an approach, therefore, would not be line with simplifying EU legislation. On a further point, the Commission is of the view that such a system would grant exclusive rights to individual operators and could hinder the free movement of products that are safe and that comply with specific legislation.

Deadlines: The Commission has accepted that the time for the European Food Safety Authority to give an opinion should be increased from six to nine months. The suggestion that the Commission should reduce the time to present a draft measure to the Standing Committee from nine to six months has been rejected.

Comitology: The Commission accepts that parts of the proposed Regulation's implementing powers should be governed by the new "regulatory procedure with scrutiny". In short, the Commission supports the amendment stating that comitology for updating the lists of food additives, food enzymes and flavourings should apply the regulatory procedure with scrutiny.

Food safety, human health protection: common authorisation procedure for food additives, food enzymes and food flavourings

2006/0143(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 establishing a common authorisation procedure for food additives, food enzymes and food flavourings. 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:

- transparency in the production and handling of food is absolutely crucial to maintain consumer confidence ;

- the criteria laid down for authorisation under the sectoral food laws should also be fulfilled for authorisation to be granted pursuant to this Regulation.
- where appropriate and under certain circumstances the specific sectoral food law may provide for protection of scientific data and other information submitted by the applicant for a certain period of time. In this case the sectoral food law should lay down the conditions under which these data may not be used for the benefit of another applicant;
- Parliament stressed that the common procedure should contribute to the free movement of food within the Community and to a high level of protection of human health and to a high level of consumer protection, including protection of consumer interests;
- the Authority shall give its opinion within nine months (instead of six months) of receipt of a valid application;
- lastly, in the Regulation updating the Community list, the Commission must explain the considerations on which it is based.

Food safety, human health protection: common authorisation procedure for food additives, food enzymes and food flavourings

2006/0143(COD) - 16/12/2008 - Final act

PURPOSE: to establish a common authorisation procedure for food additives, food enzymes and food flavourings in order to ensure the proper functioning of the internal market, while also ensuring a high level of protection of human life and health.

LEGISLATIVE ACT: Regulation (EC) No 1331/2008 of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings

CONTENT: the Council adopted a Regulation establishing a common authorisation procedure for food additives, food enzymes and food flavourings following agreement reached with the Parliament at second reading.

The new legislative act establishes a common authorisation procedure which is intended to be effective, short and transparent, based on an assessment of safety in terms of human health carried out by the European Food Safety Authority (EFSA) and a risk management exercise in which the Commission and the Member States are involved in the context of a regulatory committee procedure with a right of scrutiny by the European Parliament. The Commission must draw up, update and publish a Community list for each category of substance concerned. The inclusion of a substance on one of these lists implies that it is authorised for general use by all operators in the Community market.

The legislation provides that the common procedure will lay down the procedural

arrangements for updating the lists of substances the marketing of which is authorised in the Community pursuant to Regulation (EC) No 1333/2008 on [food additives](#), Regulation (EC) No 1332/2008 on [food enzymes](#) and Regulation (EC) No 1334/2008 on [flavourings](#). These are referred to as the sectoral food laws.

Under each sectoral food law, substances that have been authorised to be placed on the Community market shall be included on the Community list.

The deadlines laid down in the procedure take into account the time needed to consider the different criteria set in each sectoral food law, as well as allowing adequate time for consultation when preparing the draft measures. In particular, the nine-month deadline for the Commission to present a draft regulation updating the Community list should not preclude the possibility of this being done within a shorter period.

The common authorisation procedure for the substances must fulfil transparency and public information requirements while guaranteeing the right of applicants to preserve the confidentiality of certain information.

ENTRY INTO FORCE: 20/01/2009.

Food safety, human health protection: common authorisation procedure for food additives, food enzymes and food flavourings

2006/0143(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 and strengthen the key principles of the initial proposal, namely the transparency of the procedure and the environmental aspects in the food legislation.

The most important amendment concerns the introduction of a recital which clarifies that, in the future, derogations to the common authorisation procedure can be introduced in individual sectoral texts to allow for preferential authorisation under certain conditions. Another amendment increases the deadline for EFSA to perform the safety assessment of a substance from six to nine months.

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

Food safety, human health protection: common authorisation procedure for food additives, food enzymes and food flavourings

2006/0143(COD) - 10/03/2008 - Council position

The Council's common position introduced several changes to the initial proposal, some of them inspired by amendments proposed by the European Parliament. Of the 31 amendments proposed by Parliament in July 2007, the Council has incorporated, in full or in principle, 11 of them in its common position.

Amendments accepted:

Procedures: The Council agrees to introduce the regulatory procedure with scrutiny as well as the "urgency procedure" for the removal of substances from the list of authorised substances and for adding, changing or removing conditions for the use in order to protect human health. In addition, the efficiency procedure has been introduced for adding a substance to the Community list and for adding, removing or changing conditions, specifications or restrictions associated with the presence of the substance on the Community list.

Smoke flavourings: The common position clarifies that authorisation for smoke flavourings will be excluded from the scope of the proposed Regulation.

Environmental Protection: The common position clarifies that risk management will also need to take account of other legitimate factors, such as the environment.

Confidentiality: The Council clarifies what can be kept confidential for the purpose of maintaining competitiveness.

Member State information: The Council accepts that the Member States should be provided with information on what stage the procedure is at. Parliamentary amendments referring to the principle of "exceptional extension of deadlines" has been incorporated into Article 10.

Amendments not introduced:

Those amendments that have not been taken on board in the common position, refer, in summary to:

Issues that are already regulated elsewhere: This refers to independent risk assessment, given that transparency in the context of handling food is of a general nature. Under Regulation (EC) No178/2002, the primary responsibility for food safety rests with food business operators.

Stakeholder consultation: Amendments proposed by Parliament relating to stakeholder consultation have been rejected on the grounds that other legislative acts already cover such requirements. For example, Regulation 178/2002 as well as other documents of a general nature.

Criteria for authorisation: The Council has decided that any new provisions relating to the general criteria for the authorisation of substances for each sector is a repetition of what general legislation already provides for.

Reference to consumer protection and public health: The proposal already deals with procedural arrangements for updating the list of authorised substances. References that take account of human health, consumer interests and fair practices in food trade and taking account of the environment, are set out in the proposed Regulations for each sector.

Data protection: The Council argues that a provision on the protection of data would complicate administrative procedures and is thus not compatible with the principle of regulatory simplification. As a result, amendments referring to data protection, have not been incorporated into the common position.

Deadline for an EFSA opinion: Although proposed by the Parliament, the Council has decided not to extend the time limit for an EFSA opinion from 6 to 9 months.

Extension of the 6 months deadline when additional information is required: The common position extends the deadline in justified cases only.

To conclude, the Council is of the view that the common position represents a balance of concerns and interests that respects the Regulation's core objectives. It looks forward to a constructive discussion with the European Parliament with a view to the early adoption of the Regulation.

Food safety, human health protection: common authorisation procedure for food additives, food enzymes and food flavourings

2006/0143(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 safety, human health protection: common authorisation procedure for food additives, food enzymes and food flavourings

2006/0143(COD) - 10/07/2007 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted a resolution drafted by Asa WESTLUND (PES, SE), and made some amendments to the Commission's proposal:

- **scope:** an amendment was introduced whereby the Regulation would not apply to products permitted under Regulation (EC) No 2065/2003 on smoke flavourings used or intended for use in or on foods;

- **Community list:** the Community list will be **updated by the Commission in accordance with the regulatory procedure with scrutiny** provided for in Article 5a of Decision 1999/468/EC. Substances included on the Community list may be used by all food business operators subject to the conditions applicable to them, provided their use is not restricted under the terms of the legislation. When updating the Community list, the Commission must justify its draft regulation and explain the considerations on which it is based. Where the draft regulation is not in accordance with the opinion of the Authority, the Commission shall explain the reasons for its decision;

- **transparency:** an application to update the Community list will be made available by the Commission to the European Parliament, to the Member States and to stakeholders. Where it initiates the procedure on its own initiative, the Commission shall inform the Member States and make public the fact. The opinion shall also be made public, subject to certain provisos;

- **time limits:** the Authority shall give its opinion within nine months (rather than six) of receipt of a valid application. Within six months of the Authority giving its opinion, the Commission shall submit a draft regulation updating the Community list. The regulation will be adopted in accordance with the regulatory procedure with scrutiny. Where the Commission asks for further information, it may extend the time limit, and must inform the Member States of the extension;

- **scientific data and toxicological studies :** new provisions in Article 12 ensure that scientific data and other information provided by applicants may not be used for the benefit of a subsequent applicant for a period of 5 years from the date of authorisation unless the subsequent applicant has agreed with the prior applicant that such data and information may be used and costs are shared accordingly where i) the scientific data and other information were designated as proprietary by the prior applicant at the time the prior application was made, ii) the prior applicant had exclusive rights of reference to the proprietary data at the time the prior application was made, iii) the food additive could not have been authorized without the submission of the proprietary data by the prior applicant.

Food safety, human health protection: common authorisation procedure for food additives, food enzymes and food flavourings

2006/0143(COD) - 28/07/2006 - Legislative proposal

PURPOSE: to establish a common authorisation procedure for food additives, food enzymes and food flavourings in order to ensure the proper functioning of the internal market, while also ensuring a high level of protection of human life and health.

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

CONTEXT: so as to meet the objectives set in the White Paper on Food Safety, the Commission has developed, in parallel, three other proposals for Regulations that make the placing on the Community market of these substances subject to compliance with harmonised criteria and the granting of authorisation:

- Proposal for a Regulation of the European Parliament and of the Council on food additives ([COD/2006/0145](#));
- Proposal for a Regulation of the European Parliament and of the Council on food enzymes ([COD/2006/144](#));
- Proposal for a Regulation of the European Parliament and of the Council on flavourings and certain food ingredients with flavouring properties for use in and on foods ([COD/2006/0147](#)).

The new regulatory framework proposed for the substances in question must be completed by the establishment of a common authorisation procedure, insofar as the existence of different national authorisation procedures could potentially lead to different results and, in consequence, hinder the free movement of the substances concerned and distort free competition.

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

The authorisation procedure of food additives currently requires the adoption of a directive under the co-decision procedure. The Commission, believing that the co-decision procedure is too cumbersome for the regular updating of lists, suggested it should do this work itself after consulting the EC's standing committee on the food chain, made up of national experts.

Under the proposed procedure, requests for updates must be addressed to the Commission, without first going through a national authority. The Commission shall send the request file to the Authority and to the Member States and shall seek the opinion of the Authority, which must issue such opinion within six months. So as to ensure the binding effect of the updating measures, the proposal provides for their adoption to take the legal form of a regulation adopted in accordance with the comitology procedure.

The proposed measure will considerably reduce the administrative burdens on the Member States by allowing them to devote their resources particularly to implementing the legislation and to control activities.

Food safety, human health protection: common authorisation procedure for food additives, food enzymes and food flavourings

2006/0143(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 safety, human health protection: common authorisation procedure for food additives, food enzymes and food flavourings

2006/0143(COD) - 11/03/2008 - Commission communication on Council's position

The Commission supports the common position adopted unanimously by the Council in March 2008. It is in line with the aims and the approach taken in the Commission's original proposal and reflects the principles of several amendments proposed by the European Parliament.

Amendments accepted by the Commission and which are in line with the common position:

Scope: The common position, in line with Parliamentary suggestions made at first reading, clarifies that the proposed Regulation's scope will not include smoke flavourings, currently falling within the Regulation (EC) No 2065/2003 of the European Parliament and of the Council.

Confidentiality: The common position clarifies that all information related to the safety of a substance, including toxicological data, safety studies and raw data as such, should not be made confidential.

Deadlines: The Council has clarified that EFSA deadlines on opinions may be extended - even when applicants submit additional information on their own initiative. This, however, should be limited to exceptional circumstances only in accordance with Article 10. Again this modification is fully in line with Parliamentary amendments to that effect.

Transparency: In accordance with recommendations proposed by Parliament the common position modifies the initial proposal in order to strengthen provisions concerning transparency.

Regulatory procedure with scrutiny: The common position has modified the text in a bid to introduce the regulatory procedure with scrutiny and to align the proposed Regulation with Council Decision 2006/512/EC amending Decision 1999/468/EC laying down the procedures for the exercise of implementing powers conferred on the Commission. These changes correspond to several amendments put forward by Parliament. The common position differs in one respect however in that it includes the use of the curtailment of time periods in some cases. This aspect was not reflected in the Commission's amended proposal apart from the urgency procedure which was introduced for the cases of particular risk to human health.

Amendments not incorporated in the common position, which are nevertheless accepted by the Commission in the amended proposal as such or subject to rewording:

Environmental protection: The EP sought to clarify that a high level of environmental protection must be guaranteed when pursuing Community policies. Given that this principle is already included in the General Food Law (Regulation (EC) No 178/2002) the Commission decided to accept it.

Transparency: Parliamentary amendments that strengthened transparency and information provisions have been endorsed by the Commission.

EFSA deadlines: An EP amendment increasing the EFSA deadline for opinions from six to nine months has also been accepted.

New provisions introduced by Council:

Commission deadlines: The Council, contrary to Parliamentary wishes, has decided to retain a nine month Commission deadline in cases where it has to present a draft measure to update the Community list, after the EFSA opinion has been issued. For the sake of clarity, the Council has decided to introduce, in recital 9, a modification specifying that the nine months period is necessary, in some cases, for the Commission to ensure adequate consultation of stakeholders. This time-frame could be shortened depending on the nature of the draft measure. In addition, recital 10 of the common position specifies the deadline procedures. These amendments are in line with the Commission proposal and can be accepted.

Legitimate factors: The common position clarifies that other “legitimate factors” for deciding whether or not a substance should be included on the Community list, may include societal, economic, traditional, ethical and environmental factors and the feasibility of controls. These factors are already mentioned in the General Food Law, therefore reiterating them in the proposed Regulation reinforces the initial proposal and, as a result, can be accepted by the Commission.

Changes that improve the text from a technical point of view have also been made and are acceptable to the Commission.

To conclude, the Commission is of the view that the common position fully reflects the key elements of its initial proposal and the spirit of many of the amendments of the European Parliament made in the first reading. As a result it can accept the Council's common position.