Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Directive	2002/0152(COD)
Human consumption: new sweeteners additives, sucralose and salt of aspartame (amend. Directive 94/35/EC) Subject 3.10.10 Foodstuffs, foodstuffs legislation 4.60.04.04 Food safety	Procedure completed

Key players

European Parliament	Committee responsible	Rapporteur	Appointed
	ENVI Environment, Public Health, Consumer Policy		02/10/2002
		PSE FERREIRA Anne	
	Former committee responsible		
	ENVI Environment, Public Health, Consumer Policy		02/10/2002
		PSE FERREIRA Anne	
Council of the European Union	Council configuration	Meeting	Date
	Employment, Social Policy, Health and Consumer Affairs	2549	01/12/2003
	Agriculture and Fisheries	2516	25/06/2003
	Competitiveness (Internal Market, Industry, Research and Space)	2510	19/05/2003
European Commission	Commission DG	Commissioner	
	Health and Food Safety		

Key events

11/07/2002	Legislative proposal published	COM(2002)0375	Summary
02/09/2002	Committee referral announced in Parliament, 1st reading		
19/02/2003	Vote in committee, 1st reading		Summary
19/02/2003	Committee report tabled for plenary, 1st reading	A5-0049/2003	
09/04/2003	Debate in Parliament		
10/04/2003	Decision by Parliament, 1st reading	T5-0183/2003	Summary
16/05/2003	Modified legislative proposal published	COM(2003)0277	Summary

25/06/2003	Council position published	09714/1/2003	Summary
03/07/2003	Committee referral announced in Parliament, 2nd reading		
07/10/2003	Vote in committee, 2nd reading		Summary
07/10/2003	Committee recommendation tabled for plenary, 2nd reading	A5-0345/2003	
21/10/2003	Debate in Parliament		
22/10/2003	Decision by Parliament, 2nd reading	T5-0445/2003	Summary
01/12/2003	Act approved by Council, 2nd reading		
22/12/2003	Final act signed		
22/12/2003	End of procedure in Parliament		
29/01/2004	Final act published in Official Journal		

Technical information

Procedure reference	2002/0152(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Directive
Legal basis	EC Treaty (after Amsterdam) EC 095
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/5/19457

Documentation gateway

Legislative proposal		COM(2002)0375	11/07/2002	EC	Summary
Economic and Social Committee: opinion, report		CES1012/2002 OJ C 061 14.03.2003, p. 0032	18/09/2002	ESC	
Committee of the Regions: opinion		CDR0140/2002 OJ C 073 26.03.2003, p. 0034-0037	20/11/2002	CofR	
Economic and Social Committee: opinion, report		CES1356/2002 OJ C 085 08.04.2003, p. 0034-0035	11/12/2002	ESC	
Committee report tabled for plenary, 1st reading/single reading		A5-0049/2003	19/02/2003	EP	
Text adopted by Parliament, 1st reading/single reading		T5-0183/2003 OJ C 064 12.03.2004, p. 0391-0533 E	10/04/2003	EP	Summary
Modified legislative proposal		COM(2003)0277	16/05/2003	EC	Summary
Council statement on its position		10422/2003	20/06/2003	CSL	
Council position		09714/1/2003 OJ C 277 18.11.2003, p. 0001-0009 E	25/06/2003	CSL	Summary
Commission communication on Council's position		SEC(2003)0783	02/07/2003	EC	Summary

Committee recommendation tabled for plenary, 2nd reading		A5-0345/2003	07/10/2003	EP	
Text adopted by Parliament, 2nd reading		T5-0445/2003 OJ C 082 01.04.2004, p. 0269-0288 E	22/10/2003	EP	Summary
Commission opinion on Parliament's position at 2nd reading		COM(2003)0780	09/12/2003	EC	Summary

Additional information

European Commission	EUR-Lex

Final act

Directive 2003/115
OJ L 024 29.01.2004, p. 0065-0071 Summary

Human consumption: new sweeteners additives, sucralose and salt of aspartame (amend. Directive 94/35/EC)

PURPOSE : to amend Directive 94/35/EC, adding to the list of sweeteners in food. CONTENT : Directive 94/35/EC on sweeteners for use in foodstuffs sets out a list of authorised sweeteners, the foodstuffs in which they may be used and their conditions for use. It needs to be adapted in the light of recent technical and scientific developments. The major amendments proposed are as follows: -authorization of two new sweeteners: sucralose and the salt of aspertame and acesulfame. The first is a sweetener manufactured by controlled chlorination of sucrose and around 500-600 times sweeter than sugar. It is currently approved in several other countries, including Canada, Australia, Japan and the US. The manufacturer claims several specific benefits for sucralose, when compared with other sweeteners currently authorised, including the fact that its flavour profile indicates that is very similar to sugar, with less side or after tastes often associated with intense sweeteners. It blends well with sugars, is stable during high temperature processing and during long term storage. The salt of aspertame and acesulfame is a salt of two already authorised sweeteners, aspertame and acesulfame K. It is manufactured from these two substances by replacing the potassium ion of acesulfame K by aspertame. The Scientific Committee on food has stated that the use of the substance raises no additional safety concerns. The manufacturer has claimed several benefits for the salt of aspertame and acesulfame when compared with the blend of these two substances. Amongst these is the fact that the component sweeteners cannot separate and a fixed ration is guaranteed, which leads to more consistent product quality. The use of the salt is consequently proposed for the food categories where both aspertame and acesulfame K are authorised. The usable doses for the salt are derived from the lower of the usable doses for the two constituent parts, aspertame and acesulfame K. The maximum usable doses for the latter will, however, not be exceeded by their use in combination with the salt. -monitoring of authorised sweeteners, reduction of the intake of cyclamates. The Scientific Committee on Food has re-evaluated the safety of cyclamic acid and its sodium and calcium salts. It is proposed to reduce the maximum usable dose for cyclamates by banning or reducing its use in certain food categories. -the Commission will have the power to decide whether a substance is a sweetener within the meaning of this directive. ?

Human consumption: new sweeteners additives, sucralose and salt of aspartame (amend. Directive 94/35/EC)

The committee adopted the report by Anne FERREIRA (PES, F) amending the proposal under the codecision procedure (1st reading). After a heated debate, the committee voted to reduce the maximum doses of cyclamates in soft drinks from the level of 350 mg/l proposed by the Commission to 250 mg/l and to extend the new limit to milk-based drinks in addition to water-based drinks. The report called for the use of two new sweeteners authorised in the proposal (sucralose and aspartame-acesulfame salt) to be reviewed within three years, with particular attention being focused on the effects on children's health. It also said that the use of two other artificial sweeteners, aspartame and Stevia, should be re-examined and called for proposals to improve the labelling of products containing aspartame. Lastly, the committee said that the new directive should be implemented in the Member States within a year of its entry into force.?

Human consumption: new sweeteners additives, sucralose and salt of aspartame (amend. Directive 94/35/EC)

The European Parliament adopted the resolution by Mrs Anne FERREIRA (PES, F) calling on the Commission to tighten up the new restrictions it is proposing on cyclamates in soft drinks in line with its consistent drive to make sure that foodstuffs and drinks consumed in the EU are safe. It is concerned at claims that cyclamates, used as low-calorie sweeteners in drinks consumed in large quantities by children and teenagers in particular, pose health hazards and may cause reduced testosterone levels in rats and are carcinogenic. It believes that the Commission's plan to reduce the maximum levels of cyclamates from the current level of 400 mg/l to 350 mg/l. does not go far enough. The House passed an amendment which reduces the limit to 100 mg/l (and brings it down further from the limit of 250 mg/l previously demanded

by the Environment Committee). It also voted to extend the new limit to milk-based drinks in addition to water-based drinks. The resolution, which was adopted by 440 votes to 20, with 13 abstentions, accepts the Commission's proposal, in the same draft directive, to authorise two new sweeteners, sucralose and aspartame-acesulfame salt. However, it calls for a review of their use within three years. It also wants the use of two other sweeteners, aspartame and Stevia, to be re-examined and calls for proposals to improve the labelling of products containing aspartame. Parliament also wants the new directive to be implemented in the Member States within a year of its entry into force.?

Human consumption: new sweeteners additives, sucralose and salt of aspartame (amend. Directive 94/35/EC)

The Commission's amended proposal fully incorporated 2 of the 8 amendments adopted by the European Parliament at first reading: the amendment concerning the recital on cyclamates and the amendment on the transposition of the directive. The Commission rejected the other amendments. The Commission had agreed to an amendment tabled by Parliament for the plenary requesting to reduce the maximum permitted dose of cyclamates for soft drinks to 250 mg/l and to extend this limit to milk and juice based drinks. This amendment had been deleted when Parliament adopted an amendment in the plenary requesting a value of 100 mg/l for these food categories. In keeping with its position expressed in the plenary, the Commission now proposed to reduce the dose of cyclamates to 250 mg/l in soft drinks and to extend this reduction to milk and juice based drinks.?

Human consumption: new sweeteners additives, sucralose and salt of aspartame (amend. Directive 94/35/EC)

The common position is based on the Commission's amended proposal that took several amendments proposed by the European parliament into account. It has been adopted by the Council by unanimity. The Council has accepted - either word by word or in substance - the two European Parliament's amendments as set out in the Commission's amended proposal. It has however changed the deadline for the prohibition of use of products not conforming with the Directive to 18 months after the entry into force. Furthermore, the Council has followed the Commission's amended proposal in reducing the authorised levels for cyclamates for water-based drinks as well as drinks based on milk or fruit-juice as proposed by the European Parliament, to 250 mg/l. While this level is greater than the 100 mg/l proposed by the European Parliament, the Commission has undertaken in a minutes statement to keep under review the maximum usable doses of these substances, taking account inter-alia of information on intakes from Member States. As regards the other amendments, the Council, like the Commission, considers that some of the questions addressed by these amendments could be raised in the context of the future updating of the legislation. The main innovations introduced by the Council with regard to the Commission's amended proposal relate to: - clarification of the wording of Article 4 of Directive 94/35/EC, notably as regards the use of a food additive listed in the Annex and authorised at 'quantum satis' (Article 1(1)), - labelling obligation as regards salt of aspartame and acesulfame (Article 1(2)), - simplification of the layout of the table in the Annex related to the maximum usable dose for salt of aspartame-acesulfame, in order to indicate the limits either as acesulfame-K equivalents or as aspartame equivalents. Other modifications have been made, of a purely technical nature and aiming at clarifying the text of the Directive (notably concerning the renaming of certain categories and foodstuffs in the Annex, following the adoption of a certain number of Directives since 1994).?

Human consumption: new sweeteners additives, sucralose and salt of aspartame (amend. Directive 94/35/EC)

The common position is based on the amended Commission proposal that took several amendments proposed by the European Parliament into account. It has been adopted by the Council by unanimity. The Commission accepted 2 amendments adopted by the European Parliament at its first reading. Of these 2 amendments, the common position takes one into account. The common position does not include European Parliament amendments that were rejected by the Commission. Additional changes have been included in the common position as a result of discussions in the Council. Furthermore, as explained below, the Commission and the Council have moved towards the European Parliament concerning the maximum permitted level for cyclamates in soft drinks and milk and juice based drinks. The two amendments accepted by the Commission of the European Parliament without changes: One concerning the recital on cyclamates and the other concerning the delays for the transposition of the Directive. The common position takes over the amendment concerning the recital on cyclamates. The Parliament adopted a further amendment lowering the maximum permitted dose for cyclamate for soft drinks to 100 mg/l and extending this reduction to milk and juice based drinks. The Commission could not accept the value voted by the Parliament. However, the Commission proposed in its amended proposal a further reduction and extended this reduction to milk and juice based drinks (250 mg/l). The common position follows the Commission amended proposal in this matter. In the light of the above comments, the Commission agrees with the common position by the Council with a view of the adoption of a Directive of the European Parliament and of the Council amending Directive 94/35/EC on sweeteners for use in foodstuffs. The Commission's declarations to the minutes of the Council are as follows: - Ad Annex point 4(a) : The Commission undertakes to keep under review the maximum usable doses of E 952 cyclamic acid and its sodium and calcium salts taking account inter-alia of information on intakes from Member States. - Ad Annex point 5 : The Commission undertakes to examine within a period of four years the sucralose consumption study results provided by the Member States in accordance with the procedures followed for the report on food additive consumption submitted in October 2001.?

Human consumption: new sweeteners additives, sucralose and salt of aspartame (amend. Directive 94/35/EC)

The committee adopted the report by Anne FERREIRA (PES, F) amending the Council's common position (under the 2nd reading of the codecision procedure) as follows: - the Commission should report to Parliament and the Council on progress made in the re-evaluations of all additives, in particular salt of aspartame-acesulfame and sucralose, within two years of the directive's entry into force. Although the

Commission had appended a declaration to the common position pledging to examine the two new sweeteners within 4 years of the directive's entry into force, the committee felt that this should be written into the legislation; - MEPs refused to allow the Commission the right, at the present stage, to decide whether a substance is a sweetener or not. They argued that this extension of the Commission's powers should only be granted at a later stage, when the entire framework legislation had been amended (the Commission was planning to bring forward draft legislation on this in the next few months); - to prevent transitional exemptions being abused, the committee said that products which do not meet the requirements of this legislation should not remain on the market more than 24 months after the legislation enters into force, whereas the Council was prepared to allow sales to continue until stocks run out. MEPs pointed out that this could lead to an artificial build-up of stocks as a means of getting round this cut-off point.?

Human consumption: new sweeteners additives, sucralose and salt of aspartame (amend. Directive 94/35/EC)

The European Parliament adopted a resolution drafted by Anne FERREIRA (PES, France) and made three amendments to the common position. (Please see the summary of 07/10/03.)?

Human consumption: new sweeteners additives, sucralose and salt of aspartame (amend. Directive 94/35/EC)

The Commission accepts all amendments by the European Parliament; These aim to : - refuses the use of the comitology procedure for deciding whether a substance should be considered as a sweetener. The Commission would have welcomed a formal tool to bring certain substances under the scope of the food additive legislation. But in the spirit of compromise, the Commission can accept this amendment and will re-table its request in the context of the amendment of the framework legislation on food additives; - require the Commission to present a progress report on the re-evaluation of additives in general and of the two new sweeteners in particular; - introduce a clause for the exhaustion of stocks of products no longer conforming to the Directive. For this, a time limit of 24 months after entry into force of the Directive is set. ?

Human consumption: new sweeteners additives, sucralose and salt of aspartame (amend. Directive 94/35/EC)

PURPOSE: the adaptation of the positive list of sweeteners established by Directive 94/35/EC. LEGISLATIVE ACT: Directive 2003/115/EC of the European Parliament and the Council amending Directive 94/35/EC on sweeteners for use in foodstuffs. CONTENT: The Council adopted in second reading the European Parliament's amendments to the proposal. The adopted Directive takes the form of the common position as amended. The Directive seeks to adapt Directive 94/35/EC concerning sweeteners for use in foodstuffs in line with recent scientific and technical progress. It provides for: - the authorisation of two new sweeteners, sucralose and the salt of aspartame and acesulfame, which have been found acceptable for use in food by the Scientific Committee on Food (SCF); - the reduction in the consumption of an already authorised sweetener, cyclamic acid and its sodium and calcium salts, (following the SCF's opinion) by reducing the acceptable daily intake (ADI) applicable to this substance; - giving the Commission the competence to decide whether a substance should be considered a sweetener within the meaning of the Directive. By 29 January 2006 at the latest, the Commission shall submit a report to the European Parliament and the Council outlining the progress made in the re-evaluations of additives under way and setting out a provisional calendar for future re-evaluations, especially those for sucralose and salt of aspartame-acesulfame. These re-evaluations shall be carried out on the basis of consumer data supplied by the Member States and shall take account of the effects of additives on vulnerable population groups. ENTRY INTO FORCE: 29/01/2004. IMPLEMENTATION: Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive in order to: - authorise trade in and use of products conforming with this Directive by 29 January 2005 at the latest, - prohibit trade in and use of products not conforming with this Directive by 29 July 2005 at the latest; however, products placed on the market before that date which do not comply with this Directive may be marketed until 29 January 2006.?