

# Procedure file

Basic information			
COD - Ordinary legislative procedure (ex-codecision procedure) Regulation		2000/0178(COD)  Procedure completed	
Protection of human health: hygiene of foodstuffs			
Subject 3.10.10 Foodstuffs, foodstuffs legislation 4.60.04.04 Food safety			
Key players			
European Parliament	Committee responsible	Rapporteur	Appointed
	ENVI Environment, Public Health, Consumer Policy		29/08/2000
		PPE-DE <a href="#">SCHNELLHARDT Horst</a>	
	Former committee responsible		
	ENVI Environment, Public Health, Consumer Policy		29/08/2000
		PPE-DE <a href="#">SCHNELLHARDT Horst</a>	
	Former committee for opinion		
	ITRE Industry, External Trade, Research, Energy		19/09/2000
		V/ALE <a href="#">LUCAS Caroline</a>	
	AGRI Agriculture and Rural Development		14/07/2000
Council of the European Union		PSE <a href="#">KINDERMANN Heinz</a>	
	PECH Fisheries		19/09/2000
		UEN <a href="#">GALLAGHER Pat the Cope</a>	
	Council configuration	Meeting	Date
European Commission	<a href="#">Environment</a>	<a href="#">2536</a>	27/10/2003
	<a href="#">Agriculture and Fisheries</a>	<a href="#">2441</a>	27/06/2002
	<a href="#">Competitiveness (Internal Market, Industry, Research and Space)</a>	<a href="#">2426</a>	21/05/2002
	<a href="#">Agriculture and Fisheries</a>	<a href="#">2402</a>	19/12/2001
	<a href="#">Agriculture and Fisheries</a>	<a href="#">2348</a>	22/05/2001
	<a href="#">Competitiveness (Internal Market, Industry, Research and Space)</a>	<a href="#">2289</a>	28/09/2000
	Commission DG <a href="#">Health and Food Safety</a>	Commissioner	

Key events			
14/07/2000	Legislative proposal published	COM(2000)0438	Summary
04/09/2000	Committee referral announced in Parliament, 1st reading		
28/09/2000	Debate in Council	<a href="#">2289</a>	
22/05/2001	Debate in Council	<a href="#">2348</a>	
19/12/2001	Debate in Council	<a href="#">2402</a>	
17/04/2002	Vote in committee, 1st reading		Summary
17/04/2002	Committee report tabled for plenary, 1st reading	<a href="#">A5-0129/2002</a>	
14/05/2002	Debate in Parliament		
15/05/2002	Decision by Parliament, 1st reading	<a href="#">T5-0234/2002</a>	Summary
21/05/2002	Debate in Council	<a href="#">2426</a>	
27/01/2003	Modified legislative proposal published	<a href="#">COM(2003)0033</a>	Summary
27/10/2003	Council position published	<a href="#">10543/2/2002</a>	Summary
15/01/2004	Committee referral announced in Parliament, 2nd reading		
08/03/2004	Vote in committee, 2nd reading		Summary
08/03/2004	Committee recommendation tabled for plenary, 2nd reading	<a href="#">A5-0131/2004</a>	
30/03/2004	Debate in Parliament		
30/03/2004	Decision by Parliament, 2nd reading	<a href="#">T5-0216/2004</a>	Summary
16/04/2004	Act approved by Council, 2nd reading		
29/04/2004	End of procedure in Parliament		
30/04/2004	Final act signed		
30/04/2004	Final act published in Official Journal		

Technical information	
Procedure reference	2000/0178(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
Legal basis	EC Treaty (after Amsterdam) EC 095; EC Treaty (after Amsterdam) EC 152
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/5/16240

Documentation gateway					

Legislative proposal		<a href="#">COM(2000)0438</a>	14/07/2000	EC	Summary
Economic and Social Committee: opinion, report		<a href="#">CES0405/2001</a> <a href="#">OJ C 155 29.05.2001, p. 0039</a>	28/03/2001	ESC	
Committee report tabled for plenary, 1st reading/single reading		<a href="#">A5-0129/2002</a>	17/04/2002	EP	
Text adopted by Parliament, 1st reading/single reading		<a href="#">T5-0234/2002</a> <a href="#">OJ C 180 31.07.2003, p. 0160-0267 E</a>	15/05/2002	EP	Summary
Modified legislative proposal		<a href="#">COM(2003)0033</a>	27/01/2003	EC	Summary
Council statement on its position		<a href="#">12133/2003</a>	09/10/2003	CSL	
Council position		<a href="#">10543/2/2002</a> OJ C 048 24.02.2004, p. 0001-0022 E	27/10/2003	CSL	Summary
Commission communication on Council's position		<a href="#">SEC(2003)1450</a>	19/12/2003	EC	Summary
Committee recommendation tabled for plenary, 2nd reading		<a href="#">A5-0131/2004</a>	08/03/2004	EP	
Text adopted by Parliament, 2nd reading		<a href="#">T5-0216/2004</a> <a href="#">OJ C 103 29.04.2004, p. 0034-0241 E</a>	30/03/2004	EP	Summary
Commission opinion on Parliament's position at 2nd reading		<a href="#">COM(2004)0340</a>	28/04/2004	EC	Summary
Implementing legislative act		<a href="#">32005R2073</a> <a href="#">OJ L 338 22.12.2005, p. 0001-0026</a>	15/11/2005	EU	Summary
Follow-up document		COM(2009)0403	28/07/2009	EC	Summary
Follow-up document		SEC(2009)1079	28/07/2009	EC	

#### Additional information

European Commission

[EUR-Lex](#)

#### Final act

[Regulation 2004/852](#)  
[OJ L 226 25.06.2004, p. 0001-0002](#) Summary

## Protection of human health: hygiene of foodstuffs

**PURPOSE** : to present a proposal for a Regulation of the European Parliament and of the Council on the hygiene of foodstuffs. **CONTENT** : this present proposal results from a recast of Community legislation on : - food hygiene as contained in Council Directive 93/43/EEC on the hygiene of foodstuffs and in a number of Council Directives on public health problems and governing the production and placing on the market of products of animal origin; - animal health aspects related to the placing on the market of products of animal origin, as contained in a number of Council Directives that partially overlap with the food hygiene Directives; - official controls on products of animal origin contained in the above product-specific Directives. These Directives (17 in total) have been gradually developed since 1964 in response to the needs of the internal market, taking into account a higher level of protection. The leitmotif throughout the recast of the hygiene rules is that food operators bear the full responsibility for the safety of the food they produce. The implementation of hazard analysis and control principles and the observance of hygiene rules must ensure this safety. This is in line with the internationally accepted approach advocated by the Codex Alimentarius. In addition, provisions are made for the hygiene rules to be applied at all levels of the food chain, from primary production to the final customer. The principle objective of the general and specific hygiene rules is to ensure a high level of consumer protection with regard to food safety, taking into account in particular: - the principle that primary responsibility for food safety rests with the manufacturer; - the need to ensure food safety throughout the food chain, starting with primary production; - maintaining the cold chain for food that cannot be safely stored at ambient temperatures; - general implementation of the hazard analysis critical control points (HACCP) system which, together with the application of good hygiene practice, should reinforce the responsibility of food business operators; - that codes of good practice are a valuable instrument for guiding food business operators at all levels of the food chain on the compliance with food hygiene rules; - the need to

carry out official controls at stages of production, manufacture and placing on the market; - the establishment of microbiological criteria and temperature control requirements based on a scientific assessment of risk; - the need to ensure that imported foods are of at least the same or an equivalent health standard. The implementation of this Directive has shown that these principles remain valid and that their application can be extended to all foodstuffs. It is therefore a logical consequence of the recasting exercise to apply the rules of Directive 93/43/EEC to products of animal origin as well, which at present fall outside its scope. ?

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The committee adopted the report by Horst SCHNELHARDT (EPP-ED, D) broadly approving the proposal under the codecision procedure (1st reading), subject to a large number of amendments aimed mainly at ensuring consistency and clarity. Several amendments, for example, were designed to bring the proposed regulation into line with the text of the regulation laying down the general principles and requirements of food law, establishing the European Food Authority and laying down procedures in matters of food safety. The committee also wanted it to be specified, in Article 1, that the regulation should also apply to foodstuffs produced for export to non-EU countries. On the question of the application of the HACCP system in all food businesses, the committee wanted the HACCP principle to apply to primary production insofar as possible and said that the further introduction of HACCP practices must be encouraged. It also said that food business operators should declare all establishments under their control to the competent authority and supply all necessary information in order to keep the list of premises up to date. Moreover, the competent authority should not be required to give food business operators advance notice of any official inspections. In another amendment the committee sought to ensure that the Member States could grant exemptions to the regulation, in regions with "special geographical constraints", with a view to taking account not only of traditional methods of production, as stated in the proposal, but also of raw materials which are characteristic of the production process, provided these have no lasting effects on food hygiene. It added that such exemptions should be granted on a uniform and scientifically sound basis and be coordinated by the Commission. Lastly, the committee wanted the Commission to report to Parliament and Council on the implementation of the regulation within 5 years, rather than 7 years as originally proposed.?

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The European Parliament in its first reading, adopted a resolution drafted by Horst SCHNELHARDT (EPP-ED, Germany) on food hygiene. (Please refer to the document dated 17/04/02.) Parliament emphasised that the HACCP is an instrument to help food business operators attain a higher standard of food safety. HACCP should not be regarded as a method of self-regulation and does not replace official controls. Since application of the full HACCP system in the primary sector is currently not yet feasible from a practical point of view, the further introduction of appropriate practices must be encouraged. Successful implementation of the HACCP system will require the full cooperation and commitment of the business's employees, who must undergo training. Parliament feels that food operators should bear responsibility for the food produced. A series of amendments were adopted to reflect this. Where appropriate, data on products with a specific shelf life must be kept for six months following expiry of the shelf life. A time limit of five years is prescribed for keeping data on products which do not have a shelf life. Parliament stated that exceptions should be made for local specialities. The regulation should not apply to the primary production of food for domestic use nor to the direct supply of small quantities of primary products such as honey, wild game, fish, and homegrown fruit to the final consumer or to the local retail trade. ?

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The Commission has modified its proposal in the light of certain amendments made by the European parliament. It comments as follows: - most of the proposed amendments are technical and editorial and they have largely been taken over by the Commission. - some amendments aim to bring the proposal into line with Regulation 178/2002/EC, and these have been largely taken over by the Commission. - one amendment aims to clarify that the proposal does not apply to the direct supply of small quantities of primary products to the final consumer and to the local retail trade. The Commission has followed this and clarified that local trade refers to local shops and restaurants. - Parliament opposed the use of the regulatory procedure, but the Commission will retain this part of the proposal. - the Commission accepts the amendment on microbiological criteria, temperature criteria, food safety targets and performance standards. - Parliament has generally endorsed the need for flexibility for traditional food production. It made some amendments aiming to better describe where and how flexibility applies and the Commission endorses these. - the amendments aiming to introduce the HACCP system at the level of primary production are not accepted by the Commission, since it is considered too ambitious. - certain amendments introduced on the guides to good practice are accepted, but the Commission has ensured that Community guides prevail. - amendments to the requirement for registration of food businesses with the competent, aiming to introduce flexibility and to repeal the requirement for placing the registration number on the food are accepted. - amendments defining duties for the competent authorities are not accepted since they fall outside the scope of the proposal. - the timeframe of 5 years rather than 7 years for a report on implementation is accepted. - the Regulation will enter into force one year after entry into force as stipulated by Parliament. - Annex I on primary production - Parliament amendments aim to ensure a new presentation of the duties imposed on the primary production sector and they must therefore be considered as an editorial issue. The Commission accepts the main ideas but has re-drafted many amendments. - technical requirements in Annex II - the amendments generally aim to improve the proposal from a technical point of view, but some of them may create difficulties for very small enterprises and are therefore not accepted.?

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The Council is pleased to note that the Commission accepts its common position and that the draft Regulation is consistent with many of the amendments that the European Parliament adopted at first reading. Moreover, even when the Council and the Commission could not fully accept the Parliament's amendments, the common position is often closer to the Parliament's position than the Commission's original proposal. The main amendments introduced by the Council are as follows: - Scope : the Council agrees that it is not appropriate for Community legislation to lay down hygiene rules for the direct supply of small quantities of primary products to the final consumer and local retail establishments. However, the common position makes clear that direct supply means supply by the primary producer; direct supply to

local retail establishments covers only shops and restaurants (and not wholesale or processing operations); and Member States must establish national rules for such direct supply that ensure the same level of food safety as the Regulation. It also contains an exemption for collection centres and tanneries that carry out no operations related to food production other than the storage of raw material for the production of collagen or gelatine. The Regulation laying down specific hygiene rules for food of animal origin contains appropriate rules for such establishments. - HACCP : the Council does not believe that it would be practicable, in the short term, to apply the principles of hazard analysis and critical control points (HACCP) to primary production. It agrees, however, that the Commission should review this issue and report on its conclusions within five years of entry into force of the Regulation, as part of its report on the implementation of the Regulation. The Council also agrees that HACCP requirements for other food business operators need to be flexible, so as to be practicable for all types of establishments. In particular, the Council agrees that it should be possible in certain establishments to use procedures contained in guides rather than carrying out a full application of HACCP principles. To ensure that this possibility does not undermine food safety objectives, however, it is appropriate to regulate the use of guides through comitology. - Comitology : the Council agrees that it would not be appropriate for Article 4 to impose a duty on food business operators to comply with the provisions of Annexes that could be added to the Regulation through comitology. It does not accept, however, that there should be no scope for granting exemptions or for amending the existing Annexes through comitology. The common position maintains this possibility, but contains criteria specifying the circumstances in which the Annexes could be amended. - Guides to good practice : the Council agrees that it is desirable to emphasise that all stakeholders should be involved in the development of guides to good practice for food hygiene or for the application of the HACCP principles. It also accepts the need for regular reviews of Community guides. However, since food business operators would use guides on a voluntary basis, it does not agree that it would be appropriate to establish a hierarchy between Community and national guides. - Flexibility : the Council agrees that there should be flexibility for Member States to adopt national measures adapting the detailed requirements laid down in Annex II, if this does not compromise the objectives of the Regulation. It also agrees that it is appropriate to enhance the transparency of the procedure through which Member States would exercise this flexibility, to ensure that all envisaged measures undergo a proper review. However, the Council does not believe that it is appropriate to extend the procedure to Annex I, which sets general objectives rather than laying down detailed requirements. - Date of application : the common position provides for the Regulation to apply eighteen months after the date on which all elements of the package are in force, but not before 1 January 2006. - Requirements for primary producers (Annex I) : the Council agrees that the rules for primary producers should not just apply to primary production but also to certain operations intimately associated with primary production. These operations should include: operations carried out at the place of production that do not substantially alter the nature of primary products; the transport of live animals; and the delivery of products of plant origin, fishery products and wild game from the place of production to another establishment. - Technical requirements for operations after primary production (Annex II): The common position incorporates a number of technical modifications to Annex II. Key among these are stricter equipment requirements; simpler rules on heat treatment and the transfer and generalisation of requirements that used to be specific to heat treatment; and deletion of specific rules on salting and smoking, since they did not add anything to the general requirements.?

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The committee adopted the report by Horst SCHNELLHARDT (EPP-ED, D) amending the Council's common position under the 2nd reading of the codecision procedure. It reinstated a few technical amendments adopted by Parliament at 1st reading, dealing with the specific hygiene measures to be adopted by food business operators and evidence of compliance with the rules. Other amendments allowed for the possibility of extending the areas which can be governed by guidelines (as opposed to amending the legislation) and deleted the clause giving the Commission the power to amend Annexes I and II under the comitology procedure. Lastly, MEPs said that measures should be taken to establish the cause of any diseases affecting food business employees who are likely to come into contact with food.?

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## Protection of human health: hygiene of foodstuffs

The European Parliament has adopted the four reports by Mr Horst SCHNELLHARDT (EPP-ED, D) on the reform community legislation concerning the hygiene of foodstuffs. The Parliament reintroduced amendments from the first reading which were not supported by the Commission and were not included in the Council's common position. Notable disagreements include the application of the HACCP system to primary production (Annex I of the Hygiene Package) as well as the powers of the Commission to use the comitology procedure to modify the legislation's annexes on hygiene rules applicable to primary production and other types of food business (Annex II), on the specific rules on products of animal origin (Annex II - meat (red meat, poultry and game), milk, bivalve molluscs (oysters, mussels, clams etc.) and fish and on imports of animal products from third countries (Annex III). The Parliament underlined that official controls of fresh meat should in principle be carried out by official staff. However, the Member States may allow slaughterhouse staff to perform certain specific activities under the supervision of the official veterinarian but - according to two amendments adopted by MEPs - this possibility should be restricted to poultry and rabbit meat. These two particularly controversial points supported by Parliament are contested by both the Council and the Commission. Their adoption by Parliament probably means that conciliation will be necessary. The House also adopted an amendment which calls on Member States to ensure that food business operators offer all assistance needed to ensure that official controls carried out by the competent authority can be performed effectively. They should in particular give access to all buildings, premises, installations or other infrastructures; and make available any documentation and record required under the present regulation or considered necessary by the competent authority for judging the situation.?

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## Protection of human health: hygiene of foodstuffs

The European Parliament and the Council managed to agree on a compromise text prior to the second reading of the proposal in Parliament. The amendments proposed by the European Parliament at second reading reflect the compromise reached between the two institutions and the Commission is, therefore, able to accept them all. Specifically the amendments relate, inter alia, to: - a definition of "primary production"; - clarification of the responsibilities of the food business operators; - the introduction of a statement that encourages Member States to promote the implementation of the HACCP principles at the level of primary productions; - description of the possibilities for the Commission to amend the annexes using the comitology procedure; - an editorial amendment to the comitology procedure allowing derogations from the Annexes of the regulation.?

## Protection of human health: hygiene of foodstuffs

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**PURPOSE :** to lay down general rules for food business operators on the hygiene of foodstuffs.

**LEGISLATIVE ACT :** Regulation 852/2004/EC of the European Parliament and of the Council on the hygiene of foodstuffs. (Corrigendum to the Regulation published in OJ L139 of 30 April 2004).

**CONTENT :** this Regulation imposes a requirement on food business operators to ensure that all stages of production, processing and distribution of food under their control satisfy the relevant hygiene requirements laid down in this Regulation.

The Regulation lays down general rules for food business operators on the hygiene of foodstuffs, taking particular account of the following principles:

- primary responsibility for food safety rests with the food business operator;
- it is necessary to ensure food safety throughout the food chain, starting with primary production;
- it is important, for food that cannot be stored safely at ambient temperatures, particularly frozen food, to maintain the cold chain;

- general implementation of procedures based on the HACCP principles, together with the application of good hygiene practice, should reinforce food business operators' responsibility.

Food safety is a result of several factors. This legislation lays down minimum hygiene Requirements. It also states that official controls should be in place to check food business operators' compliance and food business operators must operate food safety programmes and procedures based on the HACCP principles.

This only applies to food business operators carrying out any stage of production, processing and distribution of food after primary production and those associated operations listed in Annex I.

The HACCP principles consist of the following:

- identifying any hazards that must be prevented, eliminated or reduced to acceptable levels;
  - identifying the critical control points at the steps at which control is essential to prevent or eliminate a hazard or to reduce it to acceptable levels;
  - establishing critical limits at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards;
  - implementing effective monitoring procedures at critical control points;
  - establishing corrective actions when monitoring indicates that a critical control point is not under control;
  - establishing procedures to verify that the measures outlined above are working effectively; and - establishing documents commensurate with the nature and size of the food business to demonstrate the effective application of the measures outlined above.
- Member States must encourage the development of national guides to good practice for hygiene and for the application of HACCP principles. Community guides will be developed. The dissemination of both national and Community guides will be encouraged. Nevertheless, food business operators may use these guides on a voluntary basis.

Every food business operator must notify the appropriate competent authority of each establishment under its control that carries out any of the stages of production, processing and distribution of food, so that each such establishment might be registered.

Operators must ensure that establishments are approved by the competent authority, following at least one on-site visit, when approval is required by national or Community law.

Food imported and exported is to comply with the general requirements laid down in Regulation 178/2002 or satisfy rules that are equivalent to Community rules. This Regulation defines certain specific hygiene requirements for imported and exported food. This Regulation replaces Directive 93/43/EEC, which is repealed.

**ENTRY INTO FORCE :** 20/05/2004. The Regulation shall apply no earlier than 01/01/2006.

## Protection of human health: hygiene of foodstuffs

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**ACT :** Commission Regulation 2073/2005/EC on microbiological criteria for foodstuffs.

**CONTENT :** in order to contribute to the protection of public health and to prevent differing interpretations, it is appropriate to establish harmonised safety criteria on the acceptability of food, in particular as regards the presence of certain pathogenic micro-organisms.

Microbiological criteria also give guidance on the acceptability of foodstuffs and their manufacturing, handling and distribution processes. The use of microbiological criteria should form an integral part of the implementation of HACCP-based procedures and other hygiene control measures.

This Regulation lays down the microbiological criteria for certain micro-organisms and the implementing rules to be complied with by food business operators when implementing the general and specific hygiene measures referred to in Article 4 of Regulation 852/2004/EC. The competent authority shall verify compliance with the rules and criteria laid down in this Regulation in accordance with Regulation 882/2004/EC, without prejudice to its right to undertake further sampling and analyses for the purpose of detecting and measuring other micro-organisms, their toxins or metabolites, either as a verification of processes, for food suspected of being unsafe, or in the context of a risk analysis.

This Regulation shall apply without prejudice to other specific rules for the control of micro-organisms laid down in Community legislation and in particular the health standards for foodstuffs laid down in Regulation 853/2004/EC of the European Parliament and of the Council, the rules on parasites laid down under Regulation 854/2004/EC of the European Parliament and of the Council and the microbiological criteria laid down under Council Directive 80/777/EEC.

This Regulation shall be reviewed taking into account progress in science, technology and methodology, emerging pathogenic

micro-organisms in foodstuffs, and information from risk assessments. In particular, the criteria and conditions concerning the presence of salmonella in carcasses of cattle, sheep, goats, horses, pigs and poultry shall be revised in the light of the changes observed in salmonella prevalence.

ENTRY INTO FORCE : 11/01/2006. It shall apply from 01/01/2006.