

Basic information	
2000/0178(COD) COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	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	SCHNELLHARDT Horst (PPE-DE)	29/08/2000
	Former committee responsible	Former rapporteur	Appointed
	ENVI Environment, Public Health, Consumer Policy	SCHNELLHARDT Horst (PPE-DE)	29/08/2000
	Former committee for opinion	Former rapporteur for opinion	Appointed
	ITRE Industry, External Trade, Research, Energy	LUCAS Caroline (V/ALE)	19/09/2000
	AGRI Agriculture and Rural Development	KINDERMANN Heinz (PSE)	14/07/2000
	PECH Fisheries	GALLAGHER Pat the Cope (UEN)	19/09/2000
	Council configuration		Meetings
	Competitiveness (Internal Market, Industry, Research and Space)		2426
			2002-05-21
Competitiveness (Internal Market, Industry, Research and Space)		2289	2000-09-28
Agriculture and Fisheries		2402	2001-12-19
Agriculture and Fisheries		2348	2001-05-22
Agriculture and Fisheries		2441	2002-06-27
Environment		2536	2003-10-27

Key events			
Date	Event	Reference	Summary
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		
22/05/2001	Debate in Council		
19/12/2001	Debate in Council		
17/04/2002	Vote in committee, 1st reading		Summary
17/04/2002	Committee report tabled for plenary, 1st reading	A5-0129/2002	
14/05/2002	Debate in Parliament		
21/05/2002	Debate in Council		
27/01/2003	Modified legislative proposal published	COM(2003)0033 	Summary
27/10/2003	Council position published	10543/2/2002	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	A5-0131/2004	
30/03/2004	Debate in Parliament		
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 152 EC Treaty (after Amsterdam) EC 095
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/5/16240

Documentation gateway
European Parliament

Document type	Committee	Reference	Date	Summary
Committee report tabled for plenary, 1st reading/single reading		A5-0129/2002	17/04/2002	
Committee recommendation tabled for plenary, 2nd reading		A5-0131/2004	08/03/2004	

Council of the EU

Document type	Reference	Date	Summary
Council statement on its position	12133/2003	09/10/2003	
Council position	10543/2/2002 OJ C 048 24.02.2004, p. 0001-0022 E	27/10/2003	Summary

European Commission

Document type	Reference	Date	Summary
Legislative proposal	COM(2000)0438 	14/07/2000	Summary
Modified legislative proposal	COM(2003)0033 	27/01/2003	Summary
Commission communication on Council's position	SEC(2003)1450 	19/12/2003	Summary
Commission opinion on Parliament's position at 2nd reading	COM(2004)0340 	28/04/2004	Summary
Follow-up document	COM(2009)0403 	28/07/2009	Summary
Follow-up document	SEC(2009)1079 	28/07/2009	

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
EESC	Economic and Social Committee: opinion, report	CES0405/2001 OJ C 155 29.05.2001, p. 0039	28/03/2001	
EU	Implementing legislative act	32005R2073 OJ L 338 22.12.2005, p. 0001-0026	15/11/2005	Summary

Additional information

Source	Document	Date
European Commission	EUR-Lex	

Final act

Regulation 2004/0852
OJ L 226 25.06.2004, p. 0001-0002

[Summary](#)

Protection of human health: hygiene of foodstuffs

2000/0178(COD) - 27/01/2003 - Modified legislative proposal

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 the 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.

Protection of human health: hygiene of foodstuffs

2000/0178(COD) - 29/04/2004 - Final act

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

2000/0178(COD) - 27/06/2002

The Council reached political agreement on a proposal for a Regulation on the hygiene of foodstuffs on the basis of the Presidency compromise which the Commission endorsed; the Italian delegation indicated its intention of abstaining. The Council will not, however, formally adopt a common position until discussions on other parts of the package of hygiene proposals have made sufficient progress to guarantee the consistency of the various components of the package and of their application dates. The Council also took note of progress on the proposal for a Regulation laying down specific hygiene rules for food of animal origin. It agreed to invite the Permanent Representatives Committee to continue the proceedings on this dossier and on the other components of the hygiene package. By way of reminder, this dossier forms part of a package of five food-hygiene proposals submitted by the Commission in July 2000.

Protection of human health: hygiene of foodstuffs

2000/0178(COD) - 19/12/2003

The common position largely reflects the amendments of the European Parliament that were accepted by the Commission. In addition, the common position reflects ideas of the European Parliament that were not accepted by the Commission. These concern in particular, with regard to the possible implementation of the HACCP system at the level of primary production, the establishment of a report by the Commission, and with regard to comitology, the deletion of the possibility to add new annexes to the Regulation. The Commission agreed to these amendments of its initial proposal as a matter of compromise.

Protection of human health: hygiene of foodstuffs

2000/0178(COD) - 14/07/2000 - Legislative proposal

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 to 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.

Protection of human health: hygiene of foodstuffs

2000/0178(COD) - 27/10/2003 - Council position

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.

Protection of human health: hygiene of foodstuffs

2000/0178(COD) - 28/07/2009

Regulations (EC) No 852/2004, [No 853/2004](#) and [No 854/2004](#) contain the legal requirement for the Commission to submit a report to the European Parliament and to the Council, reviewing the experience gained from their application and, if appropriate, accompanying the report with relevant proposals, not later than 20 May 2009. In addition, Regulation (EC) No 852/2004 requires the Commission to consider if it is desirable and practicable to extend the Hazard Analysis Critical Control Point (HACCP) requirements to food business operators in the primary production area.

This report followed a thorough consultation process. It is based on information received from the competent authorities in the Member States, representatives of the food business operator and consumer organisations at European level, and the Commission's Food and Veterinary Office.

Conclusion: the report aims at presenting factually the experience gained, including the difficulties encountered, in 2006, 2007 and 2008 from the implementation of the hygiene package by all interested actors. It concludes that **overall Member States have taken the necessary administrative and control steps to ensure compliance** but that there is still room for improvement in relation to implementation. These conclusions are supported by the findings of audits and inspections carried out by the Commission's Food and Veterinary Office. Consulted stakeholders consider that the new principles

and requirements introduced by the hygiene package have had a positive impact. It also indicates the clear position expressed by the Member States and private stakeholders not to extend at present the requirement for HACCP-based procedures to food business operators carrying out primary production.

The **main difficulties** identified are in relation to: (i) certain exemptions from the scope of the hygiene Regulations; (ii) certain definitions laid down in the Regulations and the procedure for adapting those definitions; (iii) certain practical aspects concerning the approval of establishments handling foods of animal origin and the marking of such foods; (iv) the import regime for certain foods; (v) the implementation of HACCP-based procedures in certain food businesses; and (vi) the implementation of official controls in certain sectors.

This report **does not suggest any detailed solutions to the difficulties reported** and is, therefore, not accompanied by proposals. However, on the basis of the difficulties identified, the Commission will consider the need for any proposals to improve the food hygiene package.

Protection of human health: hygiene of foodstuffs

2000/0178(COD) - 15/05/2002 - Text adopted by Parliament, 1st reading/single reading

The European Parliament in its first reading, adopted a resolution drafted by Horst SCHNELLHARDT (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.

Protection of human health: hygiene of foodstuffs

2000/0178(COD) - 15/11/2005 - Implementing legislative act

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 carcases 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.

Protection of human health: hygiene of foodstuffs

2000/0178(COD) - 28/04/2004 - Commission opinion on Parliament's position at 2nd reading

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 production; - 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

2000/0178(COD) - 30/03/2004 - Text adopted by Parliament, 2nd reading

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 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.