Basic information

2002/0141(COD) COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	Procedure completed
Products of animal origin, human consumption: safety, controls. Hygiene package Repealed by 2013/0140(COD) **Subject** 3.10.10 Foodstuffs, foodstuffs legislation 4.60.04.04 Food safety	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)	02/10/2002

Former committee responsible	Former rapporteur	Appointed
ENVI Environment, Public Health, Consumer Policy	SCHNELLHARDT Horst (PPE-DE)	02/10/2002

Former committee for opinion	Former rapporteur for opinion	Appointed
ITRE Industry, External Trade, Research, Energy	The committee decided not to give an opinion.	
AGRI Agriculture and Rural Development	AUROI Danielle (V/ALE)	02/10/2002
PECH Fisheries	HUDGHTON Ian (V/ALE)	12/09/2002

Council of the European Union

Council configuration	Meetings	Date
Agriculture and Fisheries	2524	2003-07-22
Agriculture and Fisheries	2500	2003-04-08
Environment	2536	2003-10-27

European Commission

Commission DG	Commissioner

	Health and Food Safety

Key events

Date	Event	Reference	Summary
11/07/2002	Legislative proposal published	COM(2002)0377	Summary
02/09/2002	Committee referral announced in Parliament, 1st reading		
08/04/2003	Debate in Council		Summary
30/04/2003	Vote in committee, 1st reading		Summary
30/04/2003	Committee report tabled for plenary, 1st reading	A5-0156/2003	
05/06/2003	Decision by Parliament, 1st reading	T5-0254/2003	Summary
05/06/2003	Debate in Parliament		
21/10/2003	Modified legislative proposal published	COM(2003)0577	Summary
27/10/2003	Council position published	11583/1/2003	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	A5-0138/2004	
30/03/2004	Decision by Parliament, 2nd reading	T5-0219/2004	Summary
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	2002/0141(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
Amendments and repeals	Repealed by 2013/0140(COD)
Legal basis	EC Treaty (after Amsterdam) EC 152-p4
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/5/19658

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee report tabled for plenary, 1st reading/single reading		A5-0156/2003	30/04/2003	
Text adopted by Parliament, 1st reading/single reading		T5-0254/2003 OJ C 068 18.03.2004, p. 0330-0435 E	05/06/2003	Summary
Committee recommendation tabled for plenary, 2nd reading		A5-0138/2004	08/03/2004	
Text adopted by Parliament, 2nd reading		T5-0219/2004	30/03/2004	Summary

Council of the EU

Document type	Reference	Date	Summary
Council statement on its position	12133/2003	09/10/2003	
Council position	11583/1/2003 OJ C 048 24.02.2004, p. 0082-0130 E	27/10/2003	Summary

European Commission

Document type	Reference	Date	Summary
Legislative proposal	COM(2002)0377 OJ C 262 29.10.2002, p. 0449 E	11/07/2002	Summary
Modified legislative proposal	COM(2003)0577	21/10/2003	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)0342	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	CES0277/2003 OJ C 095 23.04.2003, p. 0022-0023	26/02/2003	
EESC	Economic and Social Committee: opinion, report	CES0281/2003	27/02/2003	
EU	Implementing legislative act	32005R2074 OJ L 338 22.12.2005, p. 0027-0034	05/12/2005	Summary

EU	Implementing legislative act	32005R2075 OJ L 338 22.12.2005, p. 0060-0082	05/12/2005	Summary
EU	Implementing legislative act	32005R2076 OJ L 338 22.12.2005, p. 0083-0088	05/12/2005	Summary

Additional information		
Source	**Document**	**Date**
European Commission	EUR-Lex	

Final act	
Regulation 2004/0854 OJ L 226 25.06.2004, p. 0083-0127	Summary

Products of animal origin, human consumption: safety, controls. Hygiene package

2002/0141(COD) - 29/04/2004 - Final act

PURPOSE : to lay down specific rules for the organisation of official controls on products of animal origin.

LEGISLATIVE ACT : Regulation 854/2004/EC of the European Parliament and of the Council laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption. (Corrigendum to the Regulation published in OJ L139 of 30 April 2004).

CONTENT : this Regulation applies only in respect of activities and persons to which Regulation 853/2004/EC applies. It should be noted that the performance of official controls pursuant to this Regulation is without prejudice to food business operators' primary legal responsibility for ensuring food safety, as laid down in Regulation 178/2002/EC.

Official controls on the production of meat are necessary to verify that food business operators comply with hygiene rules and respect criteria and targets laid down in Community legislation. These official controls comprise audits of food business operators' activities and inspections, including checks on food business operators' own controls.

Official veterinarians will carry out audits and inspections of slaughterhouses, game handling establishments and certain cutting plants. Member States have discretion to decide which are the most appropriate staff for audits and inspections of other types of establishments.

Official controls on the production of live bivalve molluscs and on fishery products will check for compliance with the criteria and targets laid down in Community legislation. Official controls on the production of live bivalve molluscs will in particular target relaying and production areas for bivalve molluscs and the end product. Official controls on the production of raw milk will in particular target milk production holdings and raw milk upon collection.

Products of animal origin will be imported only from a third country or a part of third country that appears on a list drawn up and updated in accordance with the procedure referred to in the Regulation.

The Commission must consult the European Food Safety Authority on matters falling within the scope of the Regulation whenever necessary.

ENTRY INTO FORCE : 20/05/04. The Regulation shall apply from 01/01/2006.

Products of animal origin, human consumption: safety, controls. Hygiene package

2002/0141(COD) - 08/04/2003

The Council took note of the progress report on the proposed Regulation laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption and agreed to invite the Committee of Permanent Representatives to continue to work on the dossier in the awaiting of the Opinion of the European Parliament expected in May 2003. Commissioner BYRNE addressed the main outstanding questions to be solved at a political level prior to a further agreement: - relationship with general control rules: the proposal contains specific rules, notably on audits and imports, applied to all products of animal origin; it will apply in addition to the proposal on official feed and food controls; - division of responsibilities : with regard to the respective role of official veterinarians and official auxiliaries concerning specific tasks in abattoirs, Commissioner BYRNE mentioned the possibility of situations where official auxiliaries could operate without the permanent presence of the official veterinarian, on the basis of a case by case approach with an assessment of risks; - involvement of company staff in meat inspections: Commissioner BYRNE reaffirmed the primary responsibility of food business operators for the safety of their products and the possibility for them to carry out certain activities in relation to meat inspection. He noted that such controls by food business operators were already successfully applied in the poultry sector and suggested to extend to other sectors provided that safety requirements are met and that permanent supervision by an official veterinarian is ensured.

Products of animal origin, human consumption: safety, controls. Hygiene package

2002/0141(COD) - 21/10/2003 - Modified legislative proposal

The Commission presents an amended proposal which takes into account more than half the amendments made by the European Parliament. A large number of the proposed amendments aim to improve the proposal from a technical and editorial point of view. Most of these amendments are welcomed by the Commission (in some cases subject to editorial changes). However, certain of these amendments unnecessarily tighten the requirements of the proposal. In other cases, more appropriate wording has been proposed in the framework of the work carried out in Council. These amendments are rejected. The principal amendments accepted are: - extra flexibility as regards official controls in small meat businesses. The concept of 'artisanal small businesses,' is rejected since it conflicts with the general food safety policy of the Commission; - certain amendments deal with introducing in the text requirements for imports that were previously contained in 'Hygiene 2'. This is in principle in line with the approach of the Commission and of the Council. However, certain detailed requirements contained in some amendments are not always consistent with the approach of the Commission and of the Council, and sometimes duplicate the Commission proposal on official feed and food controls. These are rejected. The other amendments require important redrafting; - a number of amendments aim at introducing flexibility in the system of food chain information (information from the farm that has to accompany the animals to slaughter). Some are acceptable. As regards the identification of animals in particular, animals whose identity cannot be ascertained should in principle not be slaughtered for human consumption. These amendments can therefore not be accepted. - it has been decided that health marking would be limited to red meat (thus excluding poultry and rabbits) at the level of the slaughterhouse, as it was considered that systematic official carcass-by-carcass inspection was only required at this level. Therefore, certain amendments on this cannot be accepted, as they are not in line with this approach: - the Commission text provides for the possibility of the use of company staff for certain control activities. A number of amendments have been adopted that aim at bringing this company staff very much into the sphere of the competent authority. The Commission believes these two things should be kept separate. The Commission does agree to introduce some extra requirements for the establishments using company staff in control activities; - the amendment stating that the presence of the official veterinarian in small slaughterhouses should be based on an analysis of risks, is in line with the original Commission proposal and is therefore acceptable; - nearly all the amendments that deal with the training requirements for official veterinarians and official auxiliaries can be accepted as they integrate technical specifications that are more or less in line with the general food safety policy; - a number of amendments have been tabled that specifically concern live bivalve molluscs and fishery products. Most of these concern the issue of marine biotoxins in molluscs. The Commission accepts some, but most are rejected as they aim at unnecessarilyweakening the provisions for marine biotoxins, or unnecessarily limits the freedom of action by the competent authority in case of risks; - the Commission accepts the amendments relating to: communication of the lists of approved establishments; emergency slaughter; the tasks of official auxiliaries; the approved veterinarian, and the presence of the competent authority in cutting plants.

Products of animal origin, human consumption: safety, controls. Hygiene package

2002/0141(COD) - 05/12/2005

ACT : Commission Regulation 2076/2005/EC laying down transitional arrangements for the implementation of Regulations 853/2004/EC, 854/2004/EC and 882/2004/EC of the European Parliament and of the Council and amending Regulations 853/2004/EC and 854/2004/EC.

CONTENT : Regulations 853/2004/EC, 854/2004/EC and 882/2004/EC of the European Parliament and of the Council lay down the health rules and requirements regarding food of animal origin and the official controls required.

The entry into application on 1 January 2006 of these Regulations will entail considerable changes to the rules and procedures to be followed by food operators and the competent authorities of the Member States. The application of some of these measures with immediate effect from 1 January 2006 would present practical difficulties in some cases. A period should therefore be envisaged in order to permit a smooth transition to the full implementation of the new rules and procedures.

It is appropriate that the duration of the transitional period of 4 years, ending on 31 December 2009, be fixed taking into account a first review of the new regulatory framework on hygiene scheduled within the first four years. Provision should therefore be made for a transitional period during which certain requirements laid down in those Regulations can be progressively implemented. With a view to a harmonised approach, that transitional period should in principle last four years but could, where justified, be shorter. Provision should also be made for the possibility or reviewing any of those arrangements in the light of experience gained.

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

Products of animal origin, human consumption: safety, controls. Hygiene package

2002/0141(COD) - 05/12/2005

ACT : Commission Regulation 2074/2005/EC laying down implementing measures for certain products under Regulation 853/2004/EC of the European Parliament and of the Council and for the organisation of official controls under Regulation 854/2004/EC of the European Parliament and of the Council and Regulation 882/2004/EC of the European Parliament and of the Council, derogating from Regulation 852/2004/EC of the European Parliament and of the Council and amending Regulations 853/2004/EC and 854/2004/EC.

CONTENT :

- Regulation 853/2004/EC lays down specific requirements concerning hygiene rules for food of animal origin. It is necessary to lay down certain implementing measures for meat, live bivalve molluscs, fishery products, milk, eggs, frogs' legs and snails, and processed products thereof;

- Regulation 854/2004/EC lays down specific rules for the organisation of official controls on products of animal origin intended for human consumption. It is necessary to develop certain rules and further specify other requirements;

- Regulation 882/2004/EC establishes at Community level a harmonised framework of general rules for the organisation of official controls. It is necessary to develop certain rules and further specify other requirements.

The main elements of this Regulation are as follows :

- requirements concerning food chain information for the purpose of Regulations 853/2004/EC and 854/2004/EC;

- requirements concerning fishery products for the purpose of Regulations 853/2004/EC and 854/2004EC;

- recognised testing methods for marine biotoxins for the purpose of Regulations 853/2004/EC and 854/2004/EC;

- calcium content of mechanically separated meat for the purpose of Regulation 853/2004/EC;

- lists of establishments for the purpose of Regulation 882/2004/EC;

- model health certificates for frogs' legs, snails, gelatine and collagen for the purpose of Regulation 853/2004/EC;

- derogation from Regulation 852/2004/EC for foods with traditional characteristics.

ENTRY INTO FORCE : 11/01/2006. This Regulation shall apply from 01/01/2006 with the exception of Chapters II and III of Annex V (list of approved food establishments) which shall apply from 01/01/2007.

Products of animal origin, human consumption: safety, controls. Hygiene package

2002/0141(COD) - 11/07/2002 - Legislative proposal

PURPOSE : to replace the existing Community legislation on detailed rules for the organisation of official controls on products of animal origin intended for human consumption, thus making it more coherent, more science-based and risk-based. CONTENT : the new elements (from new scientific advice that has become available, in particular on issues that relate to meat safety) aim to revise in a fundamental way the proposed Regulation on detailed rules for the organisation of official controls on products of animal origin intended for human consumption (COD/2000/0180). The Commission therefore decided, on 11 December 2001, to withdraw the proposal contained in Document and to submit a revised proposal. This proposal contains a revised version and completely replaces the previous document. The revision concerns mainly official controls of fresh meat. At the same time, the risk management measures for live bivalve molluscs as well as for milk and milk products, have been strengthened. The proposed system for official controls is characterised by the following: - it is science-based; - it addresses all known hazards that are relevant for the safety of the meat; - the official veterinarian plays a central role in the system; - it consists of official audits of the systems put in place by the operator, and also of official inspection activities; - it clearly integrates the stable-to-table approach; - it deals with the relevant animal health and animal welfare issues; - the frequency and intensity of official controls is risk-based; - it contains, for certain sectors and on certain conditions, the possibility of involvement of staff of the establishment; - it contains training requirements for all staff carrying out official controls.

Products of animal origin, human consumption: safety, controls. Hygiene package

2002/0141(COD) - 19/12/2003 - Commission communication on Council's position

The common position is broadly compatible with the amendments of the European Parliament that were accepted by the Commission. The aim of certain amendments that were not accepted by the Commission has nevertheless been taken into account in the common position, apart from those on: - the involvement of slaughterhouse staff in meat inspection, - health marking of meat, - visual inspection of certain types of pig meat.

Products of animal origin, human consumption: safety, controls. Hygiene package

2002/0141(COD) - 28/04/2004 - Commission opinion on Parliament's position at 2nd reading

The European Commission can accept those amendments, which reflect the compromise text agreed between the European Parliament, the Council and Commission prior to the second reading. Specifically, they relate to: - a technical amendment clarifying the need to proceed, in the event of the emergency slaughter of animals, to an examination of the carcase as soon as possible; - a technical amendment, which ensures that control staff, in carrying out their tasks, have free access to the premises of food businesses; - an obligation on Member States to ensure that there is sufficient control staff for performing meat inspection in slaughterhouses. Greater flexibility concerning certain control activities in small businesses. In addition, the European Parliament, proposed two amendments, limiting the possibility for slaughterhouse staff to assist the official veterinarian in carrying cut meat inspection to poultry and rabbits, excluding veal claves and fattening pigs. The Commission feels that these do not reflect the compromise text agreed between the two institutions and is therefore unable to accept them. However, in order to reach a final agreement and to avoid having to go to a conciliation procedure, the Council had accepted amendments 9 and 14 on condition the Commission issue a declaration in Annex format to the modified proposal. This too, the Commission can accept. The Annex states that: The Commission will, as soon as possible after the entry into force of the Regulation, produce a report on slaughterhouse staff assisting in meat inspection with a view to examining whether and under what conditions the system in force at present for poultry meat and rabbit meat can be extended to other species such as fattening pigs and veal calves. The report will be accompanied by a legislative proposal as appropriate.

Products of animal origin, human consumption: safety, controls. Hygiene package

2002/0141(COD) - 05/06/2003 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted a resolution drafted by Horst SCHNELLHARDT (EPP-ED, Germany) and made several amendments to the Commission's proposal. (Please see the document dated 30/04/03.) Parliament added that: - producers and operators who perform better with regard to food safety and whose products present less risk should receive a reward for their investment in the form of lower inspection costs; - the Commission must draw up lists of the third countries from which imports of products of animal origin are permitted, taking into account several specified factors; - the Commission must lay down special import conditions for each third country countries. These special import conditions must include certain specified factors; - the official veterinarian will stipulate which products may be marketed in the pet food sector in the light of Regulation 1774/2002/EC; - Member States may lay down special rules for part-time official veterinarians responsible for inspecting artisanal small businesses.

Products of animal origin, human consumption: safety, controls. Hygiene package

2002/0141(COD) - 28/07/2009 - Follow-up document

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.

Products of animal origin, human consumption: safety, controls. Hygiene package

2002/0141(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.

Products of animal origin, human consumption: safety, controls. Hygiene package

2002/0141(COD) - 05/12/2005

ACT : Commission Regulation 2075/2005/EC laying down specific rules on official controls for Trichinella in meat.

CONTENT : Regulations 853/2004/EC, 854/2004/EC and 882/2004/EC of the European Parliament and of the Council lay down the health rules and requirements regarding food of animal origin and the official controls required.

In addition to those rules, more specific requirements should be laid down for Trichinella. Meat of domestic swine, wild boar, horses and other animal species may be infested with nematodes of the genus Trichinella. Consumption of meat infested with Trichinella can cause serious disease in humans.

Consequently, this Regulation lays down measures to prevent human disease caused by the consumption of meat infested with Trichinella.

It defines:

- the obligations of competent authorities and of food business operators; sampling of carcases; derogations; trichinella examination and application of health mark; staff training; methods of detection; contingency plans; recognition of officially Trichinella-free holdings; obligations on food business operators to inform; monitoring programmes; withdrawal of official recognition of Trichinella-free holdings or regions with negligible risk;

- rules relating to import health requirements.

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

Products of animal origin, human consumption: safety, controls. Hygiene package

2002/0141(COD) - 27/10/2003 - Council position

The common position incorporates several changes compared to the Commission's original proposal. Several of these changes are consistent with the aims of amendments that the European Parliament proposed in its first-reading opinion. These changes concern the following issues : 1) Regulation on official food and feed controls (COD/2003/0030) : the Commission's original proposal contained a number of references to the Regulation on official food and feed controls, which would establish general rules for official controls on all types of food and on feed. However, it appears likely that adoption of the new food hygiene legislation will take place some time before that of the Regulation on official food and feed controls. The common position therefore contains no reference to that Regulation. Instead, it incorporates some of its provisions, particularly as regards definitions and enforcement action. 2) Scope : there are close links between the second and third Regulations in the hygiene package. The second Regulation would lay down specific hygiene rules for products of animal origin. The third Regulation provides for official controls on such products. The Council agrees that both Regulations ought to have the same scope. The common position is therefore consistent with the aim of the European Parliament amendments that seek to import into the third Regulation the scope and exemptions provided for in the second. The common position also clarifies that the performance of official controls in no way diminishes food business operators' responsibility for ensuring food safety. 3) Definitions : the common position incorporates four definitions from the proposed Regulation on official food and feed controls. In addition it: would preserve the definition of "competent authority" used in several existing veterinary Directives; provides for a definition of an "approved veterinarian" to cover private veterinarians carrying

out specific official controls on holdings; clarifies that, while "official auxiliaries" must be appointed by the competent authority, they need not be "officers" (civil servants); provides for the incorporation of certain definitions laid down in Regulation 1774/2002/EC. 4) Approval of establishments : compared to the Commission's original proposal, the common position: provides some additional flexibility as regards conditional approval, particularly for factory and freezer vessels; contains clarification concerning existing establishments and wholesale markets; incorporates and generalises provisions on enforcement that initially appeared in Annex I; and provides for Member States to make lists of approved establishments available to the public. 5) Audits : the Commission's origin proposal provided for audits in respect of fresh meat. The common position establishes audits as a general principle for all food business operators handling products of animal origin falling within the scope of the Regulation. In view of their specific expertise, it would require official veterinarians to carry out audits of slaughterhouses, game-handling establishments and certain cutting plants. It would give Member States discretion to choose the most appropriate staff for audits of other establishments. 6) Official controls in respect of fresh meat : the Council agrees that the key principles applying to official controls inrespect of fresh meat ought to appear in an Article. It also agrees that Member States should follow a risk-based approach to assess the number of official staff that need to be present on the slaughter line in any particular slaughterhouse, but does not believe that it would be appropriate to extend this assessment to cover the food business operator's staff. It further agrees that there need to be strict and clear rules determining when slaughterhouse staff may assist with official controls. In particular, when carrying out certain specific tasks related to official controls, such staff must always work under the supervision of the official veterinarian and act independently from production staff. However, the Council does not believe that it is appropriate to place unnecessary restrictions on the scope of the procedure. The common position would initially give Member States the choice of allowing slaughterhouse staff to assist with official controls on animals reared as a group under the same conditions (poultry, lagomorphs, fattening pigs and fattening veal). The system could subsequently be extended through comitology to other types of animals in the light of experience. 7) Imports : the Council agrees that it is more appropriate for procedural rules concerning imports to appear in the Regulation dealing with official controls. It also believes that the rules must have the aim of ensuring that trade between the Community and third countries respects the principle of equivalence, while not imposing unnecessary or impracticable burdens on the parties involved. The common position would therefore: - establish the general rule that no third country may appear on a list of third countries from which imports are permitted unless a Community control has taken place in that third country, while providing flexibility for cases where such a control would provide no added value; - limit the requirement for third country establishments to appear on lists drawn up and updated through a Community procedure to those establishments that are a priority for enforcement action, while not affecting the basic requirement for all establishments involved in the manufacture of products of animal origin destined for export to the Community to comply with Community food law or equivalent rules; - make special provisions for vessels to reflect the fact that they may operate far from the territory of the third country the flag of which they are flying and that the administrative arrangements applying to establishments on land might not be applicable to vessels. Since most of the provisions concerning imports are points of principle, they appear in Articles. In addition, new Annexes V and VI list certain technical details, so that these might be amended through comitology if necessary. 8) Flexibility and comitology : the Council agrees that the Regulation should, like the other hygiene Regulations, contain a procedure enabling Member States to adopt national provisions adapting certain technical provisions in a transparent manner. It believes, however, that this flexibility should only apply to Annex I, since Annexes II to VI contain rules that should remain of general application. In the context of official controls, it is also appropriate to provide for the use of the flexibility procedure to enable pilot projects to take place to try out newapproaches to hygiene controls on meat. The Council also agrees that it should be possible to lay down transitional arrangements through comitology in addition to amendments to the Annexes and implementing measures. In addition, it believes that it should be possible to grant exemptions through the same procedure. In the interest of clarity, the common position lists in a single Article a number of specific decisions that could be taken through comitology. 9) Date of application : the Council considers that the scale of the reform of food hygiene legislation requires there to be a reasonable delay between adoption of the new rules and their application. It is also necessary to ensure that all elements of the hygiene package take effect at the same time. The common position therefore 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. 10) Detailed rules for fresh meat (Annex I) : the common position incorporates a number of changes to the detailed requirements for official controls with respect to fresh meat. In particular, these rules: - no longer contain provisions that appear in the common position on the second Regulation (laying down specific hygiene rules for products of animal origin); - place greater emphasis on controls on meat from animals that have undergone emergency slaughter; - limit the scope of health marking to carcasses and part-carcasses of red meat to reflect the special role that the official veterinarian plays in such cases; - clarify the circumstances in which meat is to be declared unfit for human consumption, including meat with a pronounced sexual odour and blood; - establish a short list of official controls that only official veterinarians may carry out, rather than a long list of tasks with which official auxiliaries may assist. There would be some flexibility as regards official veterinarians' presence at slaughterhouses and game-handling establishments. The presence of at least one official veterinarian throughout ante-mortem and post-mortem inspection would remain the basic requirement, but competent authorities could adapt it on the basis of a risk assessment and under strict conditions ensuring that proper inspection takes place. With respect to training, the common position would enable competent authorities to appoint official veterinarians without testing them, if the candidate has acquired all the required knowledge as part of a university degree, or through continuing education resulting in a post-graduate qualification. However, the Council does not believe that it would be appropriate in other circumstances for competent authorities to appoint practising veterinarians as official veterinarians without testing them. The common position also slightly alters the division between theoretical and practical training for official auxiliaries, without changing the overall requirement for 900 hours of training. It no longer includes a provision providing for an increase in the number of hours by a given date, since this was a political objective rather than a legal requirement. However, the Commission has undertaken, when preparing its report on the experience gained from the implementation of the Regulation, to consider whether it would be opportune to increase the minimum training requirements for official auxiliaries. 11) Detailed rules for live bivalve molluscs (Annex II) : the Council believes that the sampling frequency for toxin analysis in live bivalve molluscs should as a general rule be weekly during harvesting periods. It agrees, however, that there should be flexibility to increase or to decrease the frequency in the light of a risk assessment. The common position contains modernised criteria for the classification of production and relaying areas. The criteria for areas of classes B and C now refer only to E.coli, since there is agreement that faecal coliforms are not a reliable indicator of faecal contamination. It would be possible to amend these criteria and to specify sampling plans, methods and analytical tolerances through comitology. 12) Detailed rules for fishery products (Annex III) : the common position contains clarification concerning official controls on the production and placing on the market of fishery products. In particular, it includes detailed rules concerning official controls of vessels, to clarify which controls are necessary and which are possible taking account of the practical and legal specificities. 13) Detailed rules for raw milk (Annex IV) : the common position contains only those requirements that are specific to official controls on the production and collection of raw milk. It no longer includes rules that would have duplicated general requirements applicable to all products of animal origin. 14) Other : to be consistent with other parts of the hygiene package, the common position would require the Commission: - to consult EFSA when necessary; and - to report on the implementation of the Regulation after five years. The common position does not reflect those of the Parliament's amendments that the Commission was not able to accept, in particular those that: - would extend health marking to meat from poultry and lagomorphs; - deal with food business operators' responsibilities; - would place undue restrictions on the scope for slaughterhouse staff to assist with official controls; - would

eliminate the possibility of visual post-mortem inspection of certain categories of fattening pigs; - anticipate the outcome of discussions that should take place in the context of negotiations on the proposed Regulation on official food and feed controls; or - would introduce specific provisions for small artisanal businesses.