Basic information

2000/0179(COD) COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	Procedure completed
Protection of human health: food of animal origin, specific hygiene rules **Subject** 3.10.08 Animal health requirements, veterinary legislation and pharmacy 4.20.05 Health legislation and policy 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 of the European Union

Council configuration	Meetings	Date
Competitiveness (Internal Market, Industry, Research and Space)	2289	2000-09-28
Competitiveness (Internal Market, Industry, Research and Space)	2426	2002-05-21
Agriculture and Fisheries	2441	2002-06-27
Agriculture and Fisheries	2402	2001-12-19
Agriculture and Fisheries	2348	2001-05-22
Agriculture and Fisheries	2468	2002-11-28

	Agriculture and Fisheries	2476	2002-12-16
	Environment	2536	2003-10-27

European Commission	Commission DG	Commissioner
	Health and Food Safety	

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	A5-0131/2002	
14/05/2002	Debate in Parliament		
15/05/2002	Decision by Parliament, 1st reading	T5-0235/2002	Summary
21/05/2002	Debate in Council		
27/06/2002	Debate in Council		
28/11/2002	Debate in Council		
27/01/2003	Modified legislative proposal published	COM(2003)0033	Summary
27/10/2003	Council position published	05420/2/2003	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	A5-0129/2004	
30/03/2004	Decision by Parliament, 2nd reading	T5-0217/2004	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	2000/0179(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/5/16241

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee report tabled for plenary, 1st reading/single reading		A5-0131/2002	17/04/2002	
Text adopted by Parliament, 1st reading/single reading		T5-0235/2002 OJ C 180 31.07.2003, p. 0160-0288 E	15/05/2002	Summary
Committee recommendation tabled for plenary, 2nd reading		A5-0129/2004	08/03/2004	
Text adopted by Parliament, 2nd reading		T5-0217/2004 OJ C 103 29.04.2004, p. 0035-0264 E	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	05420/2/2003 OJ C 048 24.02.2004, p. 0023-0081 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)0344	28/04/2004	Summary
Follow-up document	COM(2008)0430	03/11/2008	Summary

Follow-up document	COM(2009)0403	28/07/2009	Summary
Follow-up document	SEC(2009)1079	28/07/2009	
Follow-up document	COM(2024)0066	14/02/2024	

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	32005R1688 OJ L 271 15.10.2005, p. 0017-0028	14/10/2005	Summary
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 2004/0853
OJ L 226 25.06.2004, p. 0022-0082 Summary

Delegated acts

Reference	Subject
2020/2907(DEA)	Examination of delegated act
2021/2626(DEA)	Examination of delegated act
2022/2834(DEA)	Examination of delegated act
2022/2915(DEA)	Examination of delegated act
2025/2835(DEA)	Examination of delegated act
2026/2595(DEA)	Examination of delegated act

2026/2848(DEA)	Examination of delegated act

Protection of human health: food of animal origin, specific hygiene rules

2000/0179(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.

Protection of human health: food of animal origin, specific hygiene rules

2000/0179(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.

Protection of human health: food of animal origin, specific hygiene rules

2000/0179(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.

Protection of human health: food of animal origin, specific hygiene rules

2000/0179(COD) - 27/01/2003 - Modified legislative proposal

The Commission accepted many of the changes made by Parliament. It comments as follows: - the majority of the amendments made by Parliament were technical or editorial and the Commission has largely taken these up; - a number of amendments aim to bring the proposal into line with Regulation 178/2002 and these have been largely adopted; - one amendment aims to better define the scope by transferring elements of the Annexes to the articles, and this is accepted since it would give more legal certainty to food business operators; - amendments relating to flexibility designed to profit small businesses are generally endorsed; - the procedure for amending the annexes was generally accepted since it recognises the Commission's right of initiative; - the Commission improves on the section on game meat, whilst taking into account the objectives pursued by Parliament. These include exclusion from the scope the private use of game meat as well as direct supplies of small quantities to the final consumer or the local retail trade. Game meat to be placed on the market must be examined by the competent authority. The amendments also seek to ensure that there is enough flexibility in order to take account of hunting traditions that may be different between Member States. - The Regulation will apply one year after entry into force as opposed to 1.1.2004. - The amendments to Annex II generally aim to make technical improvements, but some of them risk creating unnecessary burdens for small businesses or constitute an overlap with proposal COD/2000/0178, and the Commission did not accept these.

Protection of human health: food of animal origin, specific hygiene rules

2000/0179(COD) - 15/05/2002 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted a resolution drafted by Horst SCHNELLHARDT (EPP-ED, Germany) on hygiene rules for food of animal origin with a large number of amendments. (Please refer to the document dated 17/04/02.) Parliament considered that the regulation should not apply to private use or the preparation of game meat for private use and to direct supplies of small quantities of wild game and game meat to the final consumer or to the local retail trade. Where game and game meat were supplied directly by a hunter to the consumer or retailer, this should be classified as traditional food production, for which special methods of marketing exist and to which sufficient flexibility should apply. From the point of view of public health, Parliament felt that it was not necessary to provide for an exhaustive training programme concerning the hygiene of wild game and pathology for all the hunters in the EU. There are additional guarantees in respect of salmonella that are for Sweden and Finland.

Protection of human health: food of animal origin, specific hygiene rules

2000/0179(COD) - 27/10/2003 - Council position

The common position incorporates many changes compared to the Commission's original proposal. These are often consistent with the aims of amendments that the European Parliament proposed in its first-reading opinion. These changes 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 certain products of animal origin to the final consumer and local retail establishments. The common position therefore contains provisions on the direct supply of small quantities of primary products identical to those in the common position on the first hygiene Regulation. It would also exclude the direct supply of small quantities of wild game, wild game meat or meat from poultry and lagomorphs slaughtered on the farm from the scope of the Regulation. However, it would make clear that direct supply to local retail establishments covers only shops and - except in the case of poultry and lagomorphs slaughtered on the farm - restaurants, but does not cover wholesale or processing operations; and?Member States must establish national rules for such direct supply and these rules must ensure the achievement of the objectives of the Regulation. The Council also agrees that the Regulation should not apply to composite products (that is, food containing both products of plant origin and processed products of animal origin). The general rules of the Regulation on the hygiene of foodstuffs are sufficient for such products. The common position would make clear that composite products (but not products of animal origin used to manufacture them) would fall outside the scope of the Regulation. However, the Regulation would apply to food containing products of plant origin and unprocessed products of animal origin. It would also apply to processed products of animal origin containing ingredients of plant origin that are necessary for their manufacture or to give them specific characteristics. The Council further agrees that the Regulation should not, as a general principle, apply to retail activities, since the general rules of the first Regulation would suffice for the most part. The common position would consequently make clear that the general rule excluding retail from the scope of the Regulation would not?prevent Member States from applying stricter national rules to retail activities. - Comitology : the Council Council agrees that it should not generally be possible to amend the definitions laid down under the Regulation through comitology. However, rather than including a long list of definitions in the Articles, the common position would

instead leave them in Annex I but prevent the amendment of this Annex through comitology. To provide flexibility, it would make it possible for Annexes II and III to contain technical definitions that could be amended through comitology. The common position also provides for the adoption of transitional measures through comitology and, to supplement the criteria governing amendments to Annexes II and III, contains a non-exhaustive list of circumstances in which amendments or implementing rules could be adopted through comitology. - Approval of establishments : the Council agrees that the Regulation should contain an Article setting out food business operators' obligations concerning the registration and approval of establishments and that these ought to dovetail with competentauthorities' obligations under the Regulation on official controls. In addition to providing for this, the common position would clarify that approval would not be a requirement for establishments storing products of animal origin that do not require temperature-controlled storage conditions. It would also make transitional arrangements for existing establishments. - Health and identification marking : all meat should receive a health mark. The health mark should be applied only in slaughterhouses and only to carcasses and part-carcasses of red meat, to reflect the special role that the official veterinarian plays in such cases. All other meat, and all other products of animal origin handled in approved establishments, ought instead to bear an identification mark. The common position primarily provides for this by means of cross-references to the Regulation on official controls, which would lay down rules on health marking. The common position would make clear that the specific requirements on identification marking do not affect food business operators' general duty to put in place systems and procedures to ensure traceability. - Imports : to be consistent with the Regulation's focus on food business operators' obligations, the common position does not contain procedural rules concerning imports. These appear in the common position on the Regulation on official controls. - Special guarantees : the Council agrees that the provisions on salmonella guarantees should appear in an Article. The common position would also limit the scope of such guarantees to those products of animal origin to which they currently apply in relation to Finland and Sweden, with the addition of minced poultry meat (which is not currently in free circulation within the Community);?provide flexibility to update the requirements for trade with Finland and Sweden; provide a mechanism for establishing similar temporary requirements in respect of trade with other Member States with national control programmes exceeding the minimum Community requirements concerning salmonella. - Flexibility : the Council agrees that an Article should provide 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. A recital would make clear that the structural and hygiene requirements laid down in the Regulation would apply to all types of establishments, including small businesses and mobile slaughterhouses. The general provisions on flexibility mean that there is no need to have a specific reference to mobile slaughterhouses in the body of the Regulation. The common position would also make clear that Member States could maintain or establish appropriate health measures concerning raw milk and raw cream intended for direct human consumption. - Date of application : 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. - HACCP (Annex II, Section II) : to ensure the internal coherence of the different elements of the hygiene package, the Council has moved the requirements for slaughterhouse operators to the Regulation laying down specific hygiene rules for food of animal origin. - Food chain information (Annex II, Section III) : the common position includes requirements for slaughterhouse operators concerning food chain information. - Emergency slaughter (Annex III, Section I, Chapter VI) : the common position would considerably strengthen the rules on emergency slaughter. It would, in particular?limit the emergency slaughter procedure to animals that were healthy before suffering an accident; provide for meat from animals having undergone emergency slaughter to bear a special mark; restrict the placing on the market of such meat to the Member State of slaughter (subject to national rules, which may impose additional restrictions); and oblige food business operators to follow any requirements that the official veterinarian may impose concerning the use of such meat. - Wild game (Annex III, Section IV) : the Council supports the introduction of minimum Community requirements for the training of hunters. It agrees, however, that these requirements should apply to commercial hunters only, that Member States need not organise the training themselves; and that the list of topics that training should cover should be a recommendation only. In addition to clarifying these points, the common position incorporates a number of changes aimed at simplifying and clarifying the hygiene requirements for large and small wild game. - Minced meat, meat preparations and MSM (Annex III, Section V): the common position would establish general requirements for raw material used to manufacture meat preparations. These are sufficiently flexible to make it unnecessary to provide for national derogations. The common position would set differential rules for the production and use of MSM, depending on the nature of the manufacturing process. Stricter requirements would apply to MSM manufactured using more intensive methods. Member States would have the option of imposing labelling requirements on products that are not currently in free circulation within the single market, to enable consumers to make an informed choice. - Milk and dairy products (Annex III, Section IX) : the common position would simplify the requirements for heat-treated milk. It also states that the common position also makes clear that "raw milk" does not include milk that has been heated to more than 40°C or undergone any treatment that has an equivalent effect. - Gelatine and collagen (Annex III, Sections XIV & XV) : the common position would maintain the current requirement for a document to accompany raw materials destined for the production of gelatine during transport. The common position also incorporates rules on collagen. The common position would require the Commission: to consult EFSA when necessary; and to report on the implementation of the Regulation after five years.

Protection of human health: food of animal origin, specific hygiene rules

2000/0179(COD) - 14/10/2005 - Implementing legislative act

PURPOSE: to lay down rules on the microbiological sampling of eggs and of meat from bovine, porcine animals, poultry intended for Finland and Sweden.

LEGISLATIVE ACT: Commission Regulation

CONTENT: The microbiological sampling of eggs and meat from bovine and porcine animals, and poultry, intended for Finland and Sweden, shall be carried out in accordance with the provisions laid down in the Annex to this implementing Regulation.

Microbiological testing for salmonella of the samples taken in accordance with Articles 1 to 4 shall be carried out in accordance with the most recent edition of:

(a) standard EN/ISO 6579 (15) (EN/ISO 6579); or (b) method No 71 described by the Nordic Committee on Food Analysis (NMKL) (method No 71).

Where the results of the microbiological testing are contested between Member States, the most recent edition of EN/ISO 6579 shall be regarded as the reference method.

2. However, for samples of meat from bovine and porcine animals and of meat from poultry, the following analytical methods, which shall be validated by the use of meat samples in the validation studies, may be used for the microbiological testing for salmonella:

methods that have been validated against the most recent editions of EN/ISO 6579 or of method No 71 and if a proprietary method, certified by a third party in accordance with the protocol set out in standard EN/ISO 16140 (EN/ISO 16140) or other internationally accepted protocols.

ENTRY INTO FORCE: 04/11/2005.

DATE OF APPLICATION: 01/01/2006.

Protection of human health: food of animal origin, specific hygiene rules

2000/0179(COD) - 19/12/2003

The common position is broadly compatible with the amendments of the European Parliament. The Commission is satisfied therefore to accept the common position. The Commission includes a serious of declarations on the issues of scope; salmonella guarantees; live bivalve molluscs; histamine; definitions; food chain information; emergency slaughter; wild game; minced meat, meat preparations and MSM; live bivalve molluscs; fishery products; milk; eggs and egg products.

Protection of human health: food of animal origin, specific hygiene rules

2000/0179(COD) - 14/07/2000 - Legislative proposal

PURPOSE : to present a proposal for a Regulation laying down specific hygiene rules for food of animal origin. CONTENT : the 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 and official controls on products of animal origin contained in the product specific Directives. The recast is primarily motivated by the need to ensure a high level of health protection for the different disciplines concerned. As early as 1964, it was recognised that public health protection with regard to hazards in products of animal origin was regulated in a different way in the different Member States. With regard to meat in particular, health issues were used, justifiable or not, to create and maintain barriers to intra-Community trade and with a view to protecting national markets. The matter was of such a complicated nature and possible health hazards so paramount that it was felt that the only solution to this problem was a full harmonisation of the sector, with the objective to remove barriers to trade whilst ensuring a high level of consumer protection. This resulted in Directive 64/433/EEC on health problems related to the intra-Community trade in fresh meat. The attempt was successful, although it took several years to arrive at a high level and free circulation we know today. The present proposal allows for a common basis in order to simplify the Directives which contain the specific rules. Although these specific rules have helped to maintain a high level of health protection, it must be recognised that they are sometimes unnecessarily complicated and contain repetitions of similar or identical requirements. All these deficiencies contribute to difficulties of interpretation and implementation. The method of simplifying the present hygiene rules for products in animal origin is by recasting the different Directives. This approach is suggested by the observation that a number of procedures and requirements in them are identical, almost identical or similar in nature. By condensing these, a set of rules common to all food can be identified, thus avoiding the repetition, overlap and inconsistencies occurring in the Directive in force. The remaining rules are specific to a particular product, and are kept in product-specific annexes.

Protection of human health: food of animal origin, specific hygiene rules

2000/0179(COD) - 29/04/2004 - Final act

PURPOSE : to lay down specific rules on the hygiene of food of animal origin for food business operators.

LEGISLATIVE ACT : Regulation 853/2004/EC of the European Parliament and of the Council laying down specific hygiene rules for on the hygiene of foodstuffs. (Corrigendum to the Regulation published in OJ L 139 of 30 April 2004).

CONTENT : This Regulation results from a recast of Community legislation on food hygiene as contained in Council Directive 93/43/EEC 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. The principal objectives of the recasting are to secure a high level of consumer protection with regard to food safety, in particular by making food business operators throughout the Community subject to the same rules, and to ensure the proper functioning of the internal market in products of animal origin, thus contributing to the achievement of the objectives of the common agricultural policy.

This Regulation lays down specific rules on the hygiene of food of animal origin for food business operators. These rules supplement those laid down by Regulation 852/2004/EC.

They apply to unprocessed and processed products of animal origin. The Regulation does not generally apply to food containing both products of plant origin and processed products of animal origin. However, processed products of animal origin used to prepare such food must be obtained and handled in accordance with the requirements of this Regulation.

The rules do not apply either to primary production for private domestic use or to the domestic preparation, handling or storage of food for private domestic consumption.

Moreover, where small quantities of primary products or of certain types of meat are supplied directly by the food business operator producing them to the final consumer or to a local retail establishment, national law will operate because of the close relationship between the producer and the consumer.

The requirements of Regulation 852/2004/EC are generally sufficient to ensure food safety in establishments carrying out retail activities involving the direct sale or supply of food of animal origin to the final consumer. This Regulation generally applies to wholesale activities (that is, when a retail establishment carries out operations with a view to supplying food of animal origin to another establishment). Nevertheless, with the exception of the specific temperature requirements laid down in this Regulation, the requirements of Regulation 852/2004/EC will suffice for wholesale activities consisting only of storage or transport.

The following points should be noted:

- Member States have some discretion to extend or to limit the application of the Regulation to retail under national law;

- in addition to complying with the general rules of Regulation 178/2002/EC, food business operators responsible for establishments that are subject to approval in accordance with this Regulation must ensure that all products of animal origin that they place on the market bear either a health mark or an identification mark;

- the structural and hygiene requirements laid down in this Regulation apply to all types of establishments, including small businesses and mobile slaughterhouses;

- to preserve certain hunting traditions without prejudicing food safety, the Regulation provides for training for hunters who place wild game on the market for human consumption. This enables hunters to undertake an initial examination of wild game on the spot. In these circumstances, they are not required to deliver all viscera to the game-handling establishment for post-mortem examination, if they carry out this initial examination and identify no anomalies or hazards. However, Member States are allowed to establish stricter rules within their territories to take account of specific

risks;

- the Regulation establishes criteria for raw milk pending the adoption of new requirements for its placing on the market. These criteria are trigger values, implying that, in the event of any overshooting, food business operators are to take corrective action and to notify the competent authority. The criteria do not involve maximum figures beyond which raw milk cannot be placed on the market;

- the rules of this Regulation on eggs replace those of Council Decision 94/371/EC.

ENTRY INTO FORCE : 20/05/2004. The Regulation shall apply after 01/01/2006.

Protection of human health: food of animal origin, specific hygiene rules

2000/0179(COD) - 03/11/2008 - Follow-up document

This **proposal for a Council Regulation** concerns the implementation of Regulation (EC) No 853/2004 of the European Parliament and of the Council as regards the use of antimicrobial substances to remove surface contamination from poultry carcases.

Regulation (EC) No 853/2004 lays down specific rules on the hygiene of food of animal origin for food business operators. It provides that food business operators are not to use any substance other than water to remove surface contamination from products of animal origin, unless the use of the substance has been approved in accordance with that Regulation. It provides that the use of approved substances is not to affect the obligations of food business operators to comply with the requirements of that Regulation.

- **In October 1998 and April 2003**, different scientific opinions were issued by **the Scientific Committee on Veterinary measures relating to Public Heath (SCVPH)** and concluded that the use of antimicrobial substances can contribute to the decrease of pathogens in the poultry provided those substances are used in the framework of an integrated control system of the food chain. In the framework of the EC-USA Veterinary Agreement, the USA submitted files concerning the use of four antimicrobial substances (chlorine dioxide, acidified sodium chlorite, trisodium phosphate and peroxyacids) on poultry carcases. These files were transmitted to the European Food Safety Authority (EFSA), which adopted an opinion in December 2005. EFSA concluded that the use of these substances in the described conditions does not present any risk to public health and that the use of antimicrobial solutions does not replace the need for good hygienic practices during processing of poultry carcases, particularly during handling. In a second opinion in December 2005, EFSA nevertheless pointed out that the information provided on peroxyacids indicated limited effectiveness, requiring specific conditions of use to be defined.

- **On 6 March 2008**, EFSA in its scientific opinion on the Assessment of the possible effect of the four antimicrobial treatment substances on the emergence of antimicrobial resistance concludes that there are currently no published data to conclude in whatever way on the occurrence of acquired reduced susceptibility to these substances when applied on poultry carcases and to resistance to therapeutic antimicrobials.

- **Lastly, on 31 March 2008**, **the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) and the Scientific Committee on Health and Environmental Risks (SCHER)** in their joint opinion on environmental impact and effect on antimicrobial resistance of the four substances used for the removal of microbial surface contamination of poultry carcases conclude that there is not enough information available for producing comprehensive quantitative assessments that there is an environmental concern about the possibility to disseminate or select more resistant strains and, finally, that a low environmental risk has been estimated in relation to the potential residues in the carcases.

Against this background, a draft Commission Regulation approving the use of four substances to remove surface contamination from poultry carcases and setting down the conditions under which the substances may be used was submitted to the Standing Committee of the Food Chain and Animal

Health, on 2 June 2008, for vote. The Committee delivered an opinion against the proposal: 26 Member States voted against and one Member State abstained.

Consequently, pursuant to Article 3(2) of Regulation (EC) No 853/2004 and in accordance with Article 5 of Council Decision 1999/468/EC modified by Council Decision 2006/512/EC, the Commission is submitting to the Council a proposal relating to the measures to be taken, the Council having three months in which to act by a qualified majority, and is informing the Parliament.

Protection of human health: food of animal origin, specific hygiene rules

2000/0179(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: food of animal origin, specific hygiene rules

2000/0179(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.

Protection of human health: food of animal origin, specific hygiene rules

2000/0179(COD) - 28/04/2004 - Commission opinion on Parliament's position at 2nd reading

A compromise package of amendments was submitted to the European Parliament with the endorsement of the Council. As the amendments approved by the Parliament reflect the compromise agreement reached between the three institutions, the compromise is acceptable to the Commission. The compromise package contains the following amendments: - a recital emphasising the need for the Commission to coordinate the

procedure that allows Member States to deviate from the hygiene rules in order to accommodate the needs of businesses applying traditional methods of food production; - an editorial amendment that describes the possibilities for the Commission to amend the annexes using the comitology procedure; - an editorial amendment that clarifies the obligation of hunters with regard to food safety. The Commission accordingly amends its proposal.

Protection of human health: food of animal origin, specific hygiene rules

2000/0179(COD) - 03/10/2012

PURPOSE: proposal for a Council Regulation on concerning the use of lactic acid to reduce microbiological surface contamination on bovine carcases.

CONTENT: Regulation (EC) No 853/2004 lays down specific rules on the hygiene of food of animal origin for food business operators. It provides that: (i) food business operators are not to use any substance other than water to remove surface contamination from products of animal origin, unless the use of the substance has been approved in accordance with that Regulation; (ii) the use of approved substances is not to affect the obligations of food business operators to comply with the requirements of that Regulation.

On 14 December 2010, the Commission received an application for approval of the use of lactic acid to reduce surface contamination of bovine carcases and meat.

On 26 July 2011, the **European Food Safety Authority ("EFSA") adopted a favourable scientific opinion concluding that**:

- the treatments using lactic acid for decontamination are of no safety concern, provided that the substance used complies with Union specifications for food additives;
- treatments with lactic acid provide a significant reduction of microbiological contamination compared to no treatment or to treatment with potable water and that it is unlikely that such treatments would contribute to the development of microbial resistance;
- food business operators should validate the antimicrobial efficacy of such treatments under their specific processing conditions and verify lactic acid concentration, temperature of application and other factors affecting its efficacy as a decontaminating agent;
- there are no negative implications resulting from this use of lactic acid on the environment.
- taking into account that lactic acid can provide a significant reduction of possible microbiological contamination, it is appropriate to approve its use to reduce surface contamination. Such use should however be subjected to certain conditions, and limited to the use on carcases or half carcases or quarters at the level of the slaughterhouse and it should be integrated into good hygienic practices and HACCP-based systems.

Accordingly, a **draft Commission Regulation approving the use of lactic acid** to reduce surface contamination on bovine carcases was submitted to the Standing Committee of the Food Chain and Animal Health, on 21 September 2012, for an opinion. The latter has not delivered an opinion within the time limit laid down by its Chairman, and therefore, **the Commission is proposing the following measures be adopted by Council:**

- food business operators may use lactic acid to reduce microbiological surface contamination on bovine carcases or half carcases or quarters at the level of the slaughterhouse in compliance with certain conditions set out in the Annex to the proposed Regulation;
- the use of lactic acid for surface decontamination should be limited to the use on carcases or half carcases or quarters at the level of the slaughterhouse and it should be integrated into good hygienic practices and HACCP-based systems;
- such use must not affect the food business operator's duty to comply with the requirements of Union legislation on food hygiene -as laid down in Regulations (EC) No 852/2004, No 853/2004 and No 2073/2005;
- such use should in no way be considered as a substitution for good hygienic slaughtering practices and operating procedures.