Basic information

2001/0176(COD) COD - Ordinary legislative procedure (ex-codecision procedure) Decision	Procedure completed
Public health: monitoring of zoonoses and zoonotic agents (amend. Decision 90/424/EEC, repeal. Directive 92/117/EEC) **Subject** 3.10.08.05 Animal diseases 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	PAULSEN Marit (ELDR)	13/09/2001

Former committee responsible	Former rapporteur	Appointed
ENVI Environment, Public Health, Consumer Policy	PAULSEN Marit (ELDR)	13/09/2001

Former committee for opinion	Former rapporteur for opinion	Appointed
BUDG Budgets	The committee decided not to give an opinion.	
AGRI Agriculture and Rural Development		

Council of the European Union

Council configuration	Meetings	Date
Agriculture and Fisheries	2486	2003-02-20
Agriculture and Fisheries	2377	2001-10-23
Agriculture and Fisheries	2402	2001-12-19
Agriculture and Fisheries	2441	2002-06-27
Agriculture and Fisheries	2468	2002-11-28
Agriculture and Fisheries	2456	2002-10-14
Agriculture and Fisheries	2445	2002-07-15

European

Commission DG	Commissioner

Commission	Health and Food Safety	

Key events

Date	Event	Reference	Summary
01/08/2001	Legislative proposal published	COM(2001)0452	Summary
03/09/2001	Committee referral announced in Parliament, 1st reading		
23/10/2001	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	A5-0119/2002	
14/05/2002	Debate in Parliament		
15/05/2002	Decision by Parliament, 1st reading	T5-0237/2002	Summary
27/06/2002	Debate in Council		
15/07/2002	Debate in Council		Summary
14/10/2002	Debate in Council		Summary
27/11/2002	Modified legislative proposal published	COM(2002)0684	Summary
20/02/2003	Council position published	14856/1/2002	Summary
13/03/2003	Committee referral announced in Parliament, 2nd reading		
21/05/2003	Vote in committee, 2nd reading		Summary
21/05/2003	Committee recommendation tabled for plenary, 2nd reading	A5-0194/2003	
19/06/2003	Decision by Parliament, 2nd reading	T5-0277/2003	Summary
22/07/2003	Final act signed		
17/11/2003	End of procedure in Parliament		
12/12/2003	Final act published in Official Journal		

Technical information

Procedure reference	2001/0176(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Decision
Legal basis	EC Treaty (after Amsterdam) EC 152
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/5/16238

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee report tabled for plenary, 1st reading/single reading		A5-0119/2002	17/04/2002	
Text adopted by Parliament, 1st reading/single reading		T5-0237/2002 OJ C 180 31.07.2003, p. 0161-0359 E	15/05/2002	Summary
Committee recommendation tabled for plenary, 2nd reading		A5-0194/2003	21/05/2003	
Text adopted by Parliament, 2nd reading		T5-0277/2003	19/06/2003	Summary

Council of the EU

Document type	Reference	Date	Summary
Council statement on its position	05771/2003	30/01/2003	
Council position	14856/1/2002 OJ C 090 15.04.2003, p. 0009-0024 E	20/02/2003	Summary

European Commission

Document type	Reference	Date	Summary
Legislative proposal	COM(2001)0452	01/08/2001	Summary
Modified legislative proposal	COM(2002)0684	27/11/2002	Summary
Commission communication on Council's position	SEC(2003)0276	07/03/2003	Summary
Follow-up document	COM(2009)0250	29/05/2009	Summary

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
EESC	Economic and Social Committee: opinion, report	CES0191/2002 OJ C 094 18.04.2002, p. 0018	20/02/2002	

Additional information

Source	Document	Date
European Commission	EUR-Lex	

Final act

Directive 2003/0099
OJ L 325 12.12.2003, p. 0031-0040 Summary

Public health: monitoring of zoonoses and zoonotic agents (amend. Decision 90/424/EEC, repeal. Directive 92/117/EEC)

2001/0176(COD) - 01/08/2001 - Legislative proposal

PURPOSE: To set up guidelines monitoring zoonoses and zoonotic agents. CONTENT: The proposed Directive has been set up to monitor all aspects relevant to zoonoses and zoonotic agents. In principle, no zoonoses are excluded from the scope of the Directive, other than transmissible sponigform encephalopathies for which a specific set of rules are already foreseen. The proposed Directive will monitor animal populations and, where necessary, later stages of the food chain. If agreed the Directive would oblige Member States to undertake action in monitoring zoonotic organisms in general. The list of organisms covered is based on the opinion of the Scientific Committee on Veterinary Measures relating Public Health. The collection of data would be based largely on current practices in Member States. There is also a new provision relating to common criteria for data collection. Furthermore, since the collection of human data on the incidence of zoonotic diseases is of paramount importance the proposed Directive recommends closer co-operation between human, veterinary and food safety authorities in Member States. Equally, the Directive proposes to monitor the effects of animal antibiotics on zoonotic organisms and their increasing resistance to antibiotics. A separate Chapter dealing with the monitoring of food-borne outbreaks is proposed. Currently, epidemiological data is collected by a WHO-based europe-wide system. The new measures aims to speed up data collection considered vital for food safety. Food business operators would be obliged to keep the results of testing of zoonoses and to communicate these results to the competent authority upon request. Member States shall prepare a yearly report on trends and sources of zoonoses, which they must transmit to the Commission and the European Food Authority. Lastly, the proposed Directive establishes the framework for designating the Community reference Laboratories and National Reference Laboratories.

Public health: monitoring of zoonoses and zoonotic agents (amend. Decision 90/424/EEC, repeal. Directive 92/117/EEC)

2001/0176(COD) - 19/06/2003 - Text adopted by Parliament, 2nd reading

The European Parliament adopted a resolution drafted by Marit PAULSEN (ELDR, S) approving the Council's common position.

Public health: monitoring of zoonoses and zoonotic agents (amend. Decision 90/424/EEC, repeal. Directive 92/117/EEC)

2001/0176(COD) - 20/02/2003 - Council position

The common position was adopted by a qualified majority, with the German and Greek delegations abstaining. As a consequence, the common position adopted by the Council encompasses the bulk of the amendments that the Parliament adopted at first reading. The Commission accepts these amendments and the other modifications made to its initial proposal. - Scope and aim of monitoring for zoonoses and zoonotic agents: The Council agrees that the monitoring of zoonoses and zoonotic agents ought, in principle, to cover all stages of the food chain, including food and feed. It also agrees that the aim of monitoring must be to collect comparable data. The common position is therefore consistent with the relevant parliamentary amendments. The common position clarifies the provisions concerning the harmonisation of Member States' monitoring systems. The aim of such harmonisation would be to lay down minimum requirements. It would concern as a priority those zoonoses and zoonotic agents in respect of which monitoring would be mandatory in all Member States. The common position also clarifies that co-ordinated monitoring programmes would be established only if data collected through routine monitoring were not sufficient. Concerning the monitoring of antimicrobial resistance, the Council agrees that the emergence of of antimicrobial resistance is alarming, that its monitoring should be a priority, and that there should be flexibility to extend the scope of such monitoring. The common position is therefore consistent with the relevant parliamentary amendments. However, rather than providing for the monitoring of zoonotic agents and other bacteriological agents, it would permit the monitoring of zoonotic agents and, insofar as they present a threat to public health, other agents. This would provide greater flexibility, while ensuring that monitoring would target those agents that present a health risk. In addition, the common position would extend the scope of the specific requirements that would apply initially to the monitoring of antimicrobial resistance to cover certain products of animal origin. - Timetable for reports : The Council believes that the collection and analysis of data should take place as rapidly as is practicable. The common position therefore incorporates those parliamentary amendments that are consistent with this aim 3, but not those that would have imposed unrealistic deadlines. - Food business operators' duties : The common position is consistent with the parliamentary amendment seeking to clarify that food business operators may, in principle, carry out examinations for the presence of any zoonosis or zoonotic agent subject to monitoring. In addition, to facilitate the investigation of outbreaks of food-borne diseases, it would require food business operators to preserve relevant isolates and to provide them to the competent authority on request. It would also provide for the laying down of detailed rules concerning these duties. - Comitology : The Council agrees that, while it should be possible to amend technical provisions contained in the Annexes through comitology, criteria governing such amendments ought to appear in the Articles. It also agrees that the Commission should, as appropriate, consult either the Committee on the Food Chain and Animal Health or the Committee set up underDecision 2119/98/EC. For legal

reasons, however, the Commission cannot consult both committees on the same proposal. The common position is therefore consistent with the objective of the relevant parliamentary amendments. - Consultation of the European Food Safety Authority : The common position would require the Commission to consult the European Food Safety Authority before proposing: -amendments to the lists of zoonoses and zoonotic agents subject to monitoring contained in Annex I; - amendments to the detailed rules on the monitoring of antimicrobial resistance set out in Annex II; or the establishment of co-ordinated monitoring programmes. The Council does not agree, however, that such consultation ought to be automatic. In other cases, the Commission should have some discretion, to ensure that the Authority can concentrate on those issues that are the most significant for public health. The common position is therefore not consistent with the relevant parliamentary amendment. - Community co-financing : the common position on the Regulation on the control of zoonoses provides for the Commission to report on financial issues and, if appropriate, to make proposals, within three years of its entry into force. So as not to prejudice the content of this report, and the outcome of discussions on any Commission proposals within the European Parliament and the Council, the common position on the Directive includes a consequential modification to the amendment to Article 29 of Decision 90/424/EEC. The modified amendment would provide for Community co-financing of up to 50% to be available, in principle, for any costs incurred implementing mandatory control measures, enabling the decision on the level of resources to be allocated to Community co-financing to be taken in the light of the Commission's report. - Zoonoses and zoonotic agents subject to monitoring : the Council agrees that the Directive ought to make explicit that the list of zoonoses and zoonotic agents to be monitored according to the epidemiological situation includes all viruses transmitted by arthropods (and not just by ticks). The common position therefore incorporates the relevant parliamentary amendment. The Council believes that it is premature to make the monitoring of Cryptosporidiosis mandatory in all Member States. Its monitoring should depend on the epidemiological situation. In the common position this zoonosis therefore appears in the list in Part B of Annex I. The Council accepts, however, that it should be possible to amend these lists through comitology, in particular to take account of epidemiological trends. It should also be noted the common position also incorporates parliamentary amendments: - clarifying the scope of the Directive. - requiring Member States' officials to undergo ongoing training; - providing for reports to describe methods of production, where relevant. The common position does not incorporate one amendment because the Council considers it inappropriate to require epidemiological and microbiological studies in respect of all food-borne outbreaks. It should be possible to tailor the response to the size and gravity of the outbreak. Finally, compared to the Commission's initial proposal, the common position would: - delete the definition of "communicable diseases", which was superfluous and created confusion; - to be consistent with the Regulation, enable Member States to designate more than one competent authority for the purposes of the Directive, provided that there is co-operation between the authorities and a single contact point for the Commission; - set relative dates for the transposition of the Directive and for the repeal of Directive 92/117 /EEC (six months after entry into force of the Directive), to ensure that this takes place as soon as is reasonably practicable, whatever the date of adoption of the Directive.

Public health: monitoring of zoonoses and zoonotic agents (amend. Decision 90/424/EEC, repeal. Directive 92/117/EEC)

2001/0176(COD) - 29/05/2009

The purpose of this Communication is to report on the implementation of Community provisions intended to control Salmonella and the results since adoption of Regulation (EC) No 2160/2003 on the control of Salmonella and other specified food-borne zoonotic agents and of Directive 2003/99/EC on the monitoring of zoonoses and zoonotic agents. This Communication also covers other Community legislation and activities to ensure/improve control of Salmonella along the food chain.

The European Centre for Disease Prevention and Control (ECDC) and the European Food Safety Authority (EFSA) reported 151 995 human cases of salmonellosis in 2007 in the 27 Member States of the European Union, being an incidence of 31.1 per 100 000 population. It is evident that the number of human cases is seriously underestimated and underreported. Part of the human cases was detected within the frame of 3131 food-borne outbreaks which is 64.5% of the total number of food-borne outbreaks of known origin. The *Salmonella* outbreaks affected 22 705 victims, of whom 14% were hospitalised and 23 died. *Salmonella* Enteritidis and *Salmonella* Typhimurium were responsible for 95% of outbreaks with known serotype.

The paper discusses the monitoring of salmonella in hunmans and feed, foodstuffs and animals. It also discusses the control of salmonella in feed and in animal populations and foodstuffs.

The current focus of Regulation (EC) No 2160/2003 is on controlling Salmonella in primary production of poultry and pigs. The Commission has been successful in setting reduction targets for Salmonella in line with the requirements in the legislation. In the case of pigs there is a significant delay in setting a target, due to the need to collect comparable prevalence data from all 27 Member States and to the requirement to carry out a cost/benefit analysis. A comprehensive cost/benefit analysis is considered necessary before setting a target for reduction in pigs because such reduction is not evident based on current scientific advice and experiences from certain Member States. The Commission notes that a reduction target will be established as soon as the cost/benefit analysis has been completed. Notwithstanding the delay in fixing a target for reduction, the legal framework currently in force, in particular the hygiene Regulations (Regulations (EC) No 852/2004 and 852/2004) and the Regulation on microbiological criteria in foodstuffs (Regulation (EC) No 2073/2005), already provides for a high level of food safety.

The Commission did not limit itself to the adoption of implementing provisions of the Regulation (EC) No 2160/2003, but took the initiative for additional actions needed to increase the chance of success of its approach, for example:

- by providing training to the competent authorities in the Member States and third countries;
- by convincing European stakeholders organisations actively to participate;
- by providing financial support to the Member States.

Control of Salmonella has also been integrated into a broad approach to control pathogens all along the food chain, in line with the Commission’s “farm to fork” approach and taking into account possible negative side-effects such as the increase of antimicrobial resistance.

The Commission has stepped up monitoring of Salmonella in order to check the results of its own efforts and of the efforts by Member States by collecting reference values in baseline studies, by networking laboratories and by harmonising the sampling protocol. The Commission’s table in this report shows that the number of reported salmonellosis cases in the EU25 from 2004 until 2007 has fallen.

Since Regulation (EC) No 2160/2003 on zoonoses control was adopted, the awareness and motivation of competent authorities and stakeholders to tackle Salmonella has increased significantly, often resulting in action before the Community provisions became mandatory. Furthermore, a significant reduction can be expected from 2009 (restrictions on table eggs) and from 2011 (food safety criterion on poultry meat).

Public health: monitoring of zoonoses and zoonotic agents (amend. Decision 90/424/EEC, repeal. Directive 92/117/EEC)

2001/0176(COD) - 15/07/2002

The Council held an orientation debate on the zoonoses dossier on the basis of the Presidency's questionnaire. It instructed the Permanent Representatives Committee to pursue its work on the dossier in the light of this debate, with a view to enabling the Council to reach political agreement on the proposals later in the year. The Commission presented these proposals - a directive on monitoring zoonoses and a regulation on the control of salmonella and zoonotic agents - in October 2001 with a view to revising the current regulations in order to improve the control and monitoring of these diseases transmissible from animals to man. The Danish Presidency submitted a questionnaire, which was broadly supported by several delegations, with a view to solving the outstanding issues. On the financial aspect, a cost/benefit analysis provided by the Commission when proposing specific targets to control zoonoses and a report on financial issues are envisaged. On the scope of control measures, the setting of clear criteria in the regulation to define salmonella serotypes of public health significance is suggested. The Presidency also suggests a revised timetable for the establishment of Community targets and the introduction of testing depending on animal species and stages in the food chain.

Public health: monitoring of zoonoses and zoonotic agents (amend. Decision 90/424/EEC, repeal. Directive 92/117/EEC)

2001/0176(COD) - 14/10/2002

The Council held a policy debate on this issue, on the basis of a Presidency's compromise suggestions and took note that the Spanish, Portuguese, Italian and Greek delegations still disagreed at this stage with the current wording on the financing issue. The Council agreed to instruct the Permanent Representatives Committee to pursue the in-depth examination of the dossier in order to report back to the Council at its forthcoming session with a view to reaching a possible political agreement. The Presidency's compromise addresses three key issues, whose main elements are: - Scope of control measures : the Community target established for breeding flocks of Gallus gallus for a transitional period of three years shall cover the five most frequent salmonella serotypes in human salmonellosis. For laying hens broilers and turkeys, during the above mentioned period, Community targets shall cover two serotypes with a possible extension to five serotypes; - timetable for their implementation and their financing : the dates for the implementation of the provisions on controls are expressed in months after the entry into force of the Regulation; - financing of the measures : all costs incurred implementing mandatory control measures would, in principle, be eligible for Community co-financing. However, a decision on the level of resources to be allocated would be taken at a later stage.

Public health: monitoring of zoonoses and zoonotic agents (amend. Decision 90/424/EEC, repeal. Directive 92/117/EEC)

2001/0176(COD) - 07/03/2003

The Commission accepted nearly all amendments requested by the European Parliament at its first reading and revised its proposal consequently. Nearly all amendments of the European Parliament included in the Commission proposal have been taken into account in the common position. The common position does not incorporate European Parliament amendments that were rejected by the Commission. Additional changes have been included in the common position as a result of discussions in the Council after the first reading of the European Parliament. There is no difference of opinion between the Council, the European Parliament and the Commission regarding the basic principles that the Directive should establish. In particular, the three Institutions agree that: - data need to be comparable; - monitoring should in principle cover all stages of the food chain; - the scope of the monitoring of antimicrobial resistance needs to be flexible. The Commission will propose the harmonisation of routine monitoring of zoonoses and zoonotic agents, including the harmonisation of laboratory methods to be used in testing, if and to the extent necessary to ensure that data are comparable. When doing so, it will take due account of the principles of subsidiarity and proportionality, and the need to avoid creating undue financial or administrative burdens for competent authorities. The Commission will propose measures in accordance with existing Community legislation to permit the gathering of the data needed for the adoption of the first control targets under the Regulation before the Directive takes effect. The Council and the Commission consider that the resources available need to be sufficient to cover the co-financing of measures to control zoonoses.

Public health: monitoring of zoonoses and zoonotic agents (amend. Decision 90/424/EEC, repeal. Directive 92/117/EEC)

2001/0176(COD) - 15/05/2002 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted a resolution on zoonoses and zoonotic agents drafted by Marit PAULSEN (ELDR, Sweden) with some amendments to the Commission's proposal. (Please refer to the document dated 17/04/02.) In addition, members specified that monitoring by Member States provides comparable data. Monitoring is to be coordinated with the monitoring of human isolates conducted according to Decision No 2119/98/EC.

Public health: monitoring of zoonoses and zoonotic agents (amend. Decision 90/424/EEC, repeal. Directive 92/117/EEC)

2001/0176(COD) - 27/11/2002 - Modified legislative proposal

The European Parliament adopted 30 amendments, 28 of which are accepted by the Commission. These include: - the requirement that zoonotic agents be monitored not only in animals, feed and food of animal origin, but also in food of plant origin and food of mixed origin. - strengthening the collection of comparable and uniform data on zoonoses from Member States; - a non-exhaustive list of authorities (including competent authorities for legislation on animal feed) and organisations to be included in the cooperation required in the collection of zoonoses data at the national level; - national reports will be published without delay, but the Commission cannot accept the shortening of the time allowed for Member States to submit their reports; - tightening the responsibilities of food business operators to keep relevant food samples in case of food-borne outbreaks and the testing results on zoonotic agents; - broadening the scope of the monitoring of antimicrobial resistance to agents other then zoonotic ones; - changes to comitology procedure; - making the consultation of the European Food Safety Authority compulsory when establishing coordinated monitoring programmes; - transferring criteria concerning the addition or deletion of zoonoses subject to monitoring from annex to articles. This will enable Parliament and Council to be involved if further amendments are proposed to the criteria.

Public health: monitoring of zoonoses and zoonotic agents (amend. Decision 90/424/EEC, repeal. Directive 92/117/EEC)

2001/0176(COD) - 17/11/2003 - Final act

PURPOSE : to amend and replace Directive 92/117/EEC. LEGISLATIVE ACT : Directive 2003/99/EC of the European Parliament and of the Council on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC. CONTENT : the purpose of this Directive is to ensure that zoonoses, zoonotic agents and related antimicrobial resistance are properly monitored, and that food-borne outbreaks receive proper epidemiological investigation, to enable the collection in the Community of the information necessary to evaluate relevant trends and sources. This Directive covers: - the monitoring of zoonoses and zoonotic agents; - the monitoring of related antimicrobial resistance; - the epidemiological investigation of food-borne outbreaks; and - the exchange of information related to zoonoses and zoonotic agents. This Directive shall apply without prejudice to more specific Community provisions on animal health, animal nutrition, food hygiene, communicable human diseases, health and safety in the workplace, gene technology and transmissible spongiform encephalopathies. Member States shall collect relevant and comparable data in order to identify and characterise hazards, to assess exposures and to characterise risks related to zoonoses and zoonotic agents. ENTRY INTO FORCE : 12/12/2003. IMPLEMENTATION : 12/04/2004. The Member States shall apply those measures by 12/06 /2004.