

# Procedure file

Basic information				
COD - Ordinary legislative procedure (ex-codecision procedure) Decision		2001/0176(COD)		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		13/09/2001
			ELDR	PAULSEN Marit
	Former committee responsible			
	ENVI	Environment, Public Health, Consumer Policy		13/09/2001
			ELDR	PAULSEN Marit
	Former committee for opinion			
	BUDG	Budgets		The committee decided not to give an opinion.
	AGRI	Agriculture and Rural Development		
Council of the European Union	Council configuration		Meeting	Date
	<a href="#">Agriculture and Fisheries</a>		<a href="#">2486</a>	20/02/2003
	<a href="#">Agriculture and Fisheries</a>		<a href="#">2468</a>	28/11/2002
	<a href="#">Agriculture and Fisheries</a>		<a href="#">2456</a>	14/10/2002
	<a href="#">Agriculture and Fisheries</a>		<a href="#">2445</a>	15/07/2002
	<a href="#">Agriculture and Fisheries</a>		<a href="#">2441</a>	27/06/2002
	<a href="#">Agriculture and Fisheries</a>		<a href="#">2402</a>	19/12/2001
	<a href="#">Agriculture and Fisheries</a>		<a href="#">2377</a>	23/10/2001
European Commission	Commission DG		Commissioner	
	<a href="#">Health and Food Safety</a>			

Key events			
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	<a href="#">2377</a>	
19/12/2001	Debate in Council	<a href="#">2402</a>	
17/04/2002	Vote in committee, 1st reading		Summary
17/04/2002	Committee report tabled for plenary, 1st reading	<a href="#">A5-0119/2002</a>	
14/05/2002	Debate in Parliament		
15/05/2002	Decision by Parliament, 1st reading	<a href="#">T5-0237/2002</a>	Summary
27/06/2002	Debate in Council	<a href="#">2441</a>	
15/07/2002	Debate in Council	<a href="#">2445</a>	Summary
14/10/2002	Debate in Council	<a href="#">2456</a>	Summary
27/11/2002	Modified legislative proposal published	<a href="#">COM(2002)0684</a>	Summary
20/02/2003	Council position published	<a href="#">14856/1/2002</a>	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	<a href="#">A5-0194/2003</a>	
19/06/2003	Decision by Parliament, 2nd reading	<a href="#">T5-0277/2003</a>	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

Legislative proposal		COM(2001)0452	01/08/2001	EC	Summary
Economic and Social Committee: opinion, report		<a href="#">CES0191/2002</a> <a href="#">OJ C 094 18.04.2002, p. 0018</a>	20/02/2002	ESC	
Committee report tabled for plenary, 1st reading/single reading		<a href="#">A5-0119/2002</a>	17/04/2002	EP	
Text adopted by Parliament, 1st reading/single reading		<a href="#">T5-0237/2002</a> <a href="#">OJ C 180 31.07.2003, p. 0161-0359 E</a>	15/05/2002	EP	Summary

Modified legislative proposal		<a href="#">COM(2002)0684</a>	27/11/2002	EC	Summary
Council statement on its position		<a href="#">05771/2003</a>	30/01/2003	CSL	
Council position		<a href="#">14856/1/2002</a> OJ C 090 15.04.2003, p. 0009-0024 E	20/02/2003	CSL	Summary
Commission communication on Council's position		<a href="#">SEC(2003)0276</a>	07/03/2003	EC	Summary
Committee recommendation tabled for plenary, 2nd reading		<a href="#">A5-0194/2003</a>	21/05/2003	EP	
Text adopted by Parliament, 2nd reading		<a href="#">T5-0277/2003</a>	19/06/2003	EP	Summary
Follow-up document		<a href="#">COM(2009)0250</a>	29/05/2009	EC	Summary

#### Additional information

European Commission

[EUR-Lex](#)

#### Final act

[Directive 2003/99](#)

[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)

**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 spongiform 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)

The committee adopted the report by Marit PAULSEN (ELDR, S) amending the proposal under the codecision procedure (1st reading). Some of the amendments were aimed at emphasising the importance of monitoring antimicrobial resistance, by spelling out more clearly that this was one of the specific aims of the directive. The committee also sought to ensure that the directive included the monitoring of plant products, arguing that the number of people infected through such products was increasing. MEPs stressed the need for greater cooperation among the relevant authorities, including those with responsibility for animal feed, and for more rapid reporting and publishing of information by both the Member States and the European Food Safety Authority. The committee also restructured the proposal slightly so as to include parts of the annex in the substantive part of the text. For example, it included in one of the articles the criteria for the addition or deletion of zoonoses from the list in Annex I, on the grounds that these were of fundamental importance. Finally, the committee stressed the need for comparability of the data compiled by the Member States. ?

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

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)

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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)

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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)

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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 than 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)

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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 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 under Decision 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)

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The committee adopted the report by Marit PAULSEN (ELDR, S) approving the Council's common position without amendment under the 2nd reading of the codecision procedure. ?

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

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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)

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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.?

