


# Procedure file

Basic information	
COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	2001/0177(COD) Procedure completed
Public health: control of salmonella and food-born zoonotic agents Amended by <a href="#">2013/0136(COD)</a>	
Subject 3.10.10 Foodstuffs, foodstuffs legislation 3.40.13 Food industry 4.20.05 Health legislation and policy 4.60.04.04 Food safety	

Key players			
European Parliament	Committee responsible	Rapporteur	Appointed
	<b>ENVI</b> Environment, Public Health, Consumer Policy		13/09/2001
		ELDR <a href="#">PAULSEN Marit</a>	
	Former committee responsible		
	<b>ENVI</b> Environment, Public Health, Consumer Policy		13/09/2001
		ELDR <a href="#">PAULSEN Marit</a>	
	Former committee for opinion		
	<b>BUDG</b> Budgets	The committee decided not to give an opinion.	
	<b>AGRI</b> Agriculture and Rural Development		
Council of the European Union	Council configuration	Meeting	Date
	<a href="#">Agriculture and Fisheries</a>	<a href="#">2528</a>	29/09/2003
	<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="#">2377</a>	23/10/2001
European Commission	Commission DG	Commissioner	
	<a href="#">Health and Food Safety</a>		

Key events			
31/07/2001	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>	
17/04/2002	Vote in committee, 1st reading		Summary
16/04/2002	Committee report tabled for plenary, 1st reading	<a href="#">A5-0120/2002</a>	

14/05/2002	Debate in Parliament		
15/05/2002	Decision by Parliament, 1st reading	<a href="#">T5-0236/2002</a>	Summary
15/07/2002	Debate in Council	<a href="#">2445</a>	Summary
14/10/2002	Debate in Council	<a href="#">2456</a>	Summary
26/11/2002	Modified legislative proposal published	<a href="#">COM(2002)0684</a>	Summary
19/02/2003	Council position published	<a href="#">14857/1/2002</a>	Summary
13/03/2003	Committee referral announced in Parliament, 2nd reading		
21/05/2003	Vote in committee, 2nd reading		Summary
20/05/2003	Committee recommendation tabled for plenary, 2nd reading	<a href="#">A5-0195/2003</a>	
19/06/2003	Decision by Parliament, 2nd reading	<a href="#">T5-0284/2003</a>	Summary
29/09/2003	Act approved by Council, 2nd reading		
17/11/2003	Final act signed		
17/11/2003	End of procedure in Parliament		
12/12/2003	Final act published in Official Journal		

### Technical information

Procedure reference	2001/0177(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
	Amended by <a href="#">2013/0136(COD)</a>
Legal basis	EC Treaty (after Amsterdam) EC 152
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/5/16239

### Documentation gateway

Legislative proposal	<a href="#">COM(2001)0452</a>	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="#">A5-0120/2002</a>	17/04/2002	EP	
Text adopted by Parliament, 1st reading/single reading	<a href="#">T5-0236/2002</a> <a href="#">OJ C 180 31.07.2003, p. 0160-0343 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="#">14857/1/2002</a> OJ C 090 15.04.2003, p.	20/02/2003	CSL	Summary

		0025-0043 E			
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="#">A5-0195/2003</a>	21/05/2003	EP	
Text adopted by Parliament, 2nd reading		<a href="#">T5-0284/2003</a>	19/06/2003	EP	Summary
Commission opinion on Parliament's position at 2nd reading		<a href="#">COM(2003)0434</a>	16/07/2003	EC	Summary
Implementing legislative act		<a href="#">32005R1003</a> <a href="#">OJ L 170 01.07.2005, p. 0012-0017</a>	30/06/2005	EU	Summary
Implementing legislative act		<a href="#">32005R1091</a> <a href="#">OJ L 182 13.07.2005, p. 0003-0004</a>	12/07/2005	EU	Summary
Implementing legislative act		<a href="#">32006R1168</a> <a href="#">OJ L 211 01.08.2006, p. 0004-0008</a>	31/07/2006	EU	Summary
Implementing legislative act		<a href="#">32006R1177</a> <a href="#">OJ L 212 02.08.2006, p. 0003-0005</a>	01/08/2006	EU	Summary
Follow-up document		<a href="#">COM(2009)0250</a>	29/05/2009	EC	Summary

#### Additional information

European Commission

[EUR-Lex](#)

#### Final act

[Regulation 2003/2160](#)

[OJ L 325 12.12.2003, p. 0001-0015](#) Summary

Final legislative act with provisions for delegated acts

## Public health: control of salmonella and food-born zoonotic agents

**PURPOSE:** To control salmonella and other food-borne zoonotic agents. **CONTENT:** The proposed Regulation seeks to encompass a fundamental review towards the control of zoonotic diseases. In principle all zoonotic agents would be covered by this Directive. However, the specific control requirements cover certain types of salmonella only. An extension of other pathogens would be possible should epidemiological studies justify such action. Control activities should take place primarily during primary production of animals and where necessary at subsequent stages of the food chain. The proposal creates a framework for a pathogen reduction policy for selected zoonotic agents in selected farming animal populations. Targets would be set for certain salmonella serotype in laying hens, broilers and their breeders and for turkey and pig breeders. Implementing pathogen reduction systems would be done through the establishment of national control programmes. At the same time however, the regulation encourages own-initiative actions by the private sector. Accordingly, Member States should encourage food businesses to establish their own control programmes. The Regulation further suggests that certain control methods should not be used. For example, the use of antibiotics or vaccination in animals may require future scrutiny. Concerning trade in live animals or hatching eggs, a basic element of the proposal is to ensure that the purchaser knows the status of the holding of origin of the animals. In intra-community trade there is a need to use a health certification system. As regards third countries, equivalent measures would be required for importation of relevant live animals and hatching eggs into the Community. Lastly, the proposal establishes the framework for designating the Community reference Laboratories and National Reference Laboratories and to define their respective tasks. It also lays down the quality requirements for laboratories participating in control programmes.?

## Public health: control of salmonella and food-born zoonotic agents

The committee adopted the report by Marit Paulsen (ELDR, S) amending the proposal under the codecision procedure (1st reading) with a view to broadening its scope. The committee criticised the Commission's intention, in practice, to set up control programmes only for poultry and eggs even though salmonella is common in other food-producing animals. Amendments were therefore adopted extending the measures to include slaughter pigs, sheep calves and other cattle. MEPs also sought to ensure that the directive included the monitoring of plant products, arguing that the number of zoonoses spread through such products was increasing. A further amendment stipulated that a Member

State which had not had its national control programme approved within 12 months of the Community targets being set should be prohibited from selling certain products on the internal market. The amendment aimed to ensure that negligent producers did not enjoy a financial advantage over those who complied with the rules. The committee also pointed out that the regulation would impose a substantial burden on small businesses and that the Member States should therefore take account of this fact when drawing up their national control programmes in order to achieve an appropriate distribution of costs. The committee also restructured the proposal slightly so as to include parts of the annex in the substantive part of the text. It felt that the criteria for laying down the list of zoonoses and stages in the food chain and the details of the Community targets to be achieved should be incorporated into Article 4 (Community targets for the reduction of prevalences of zoonoses and zoonotic agents) on the grounds that these were of fundamental importance and should not just be listed in the Annex. Lastly, the committee wanted one of the recitals to state that the use of antibiotics for preventive purposes or to promote growth should be prohibited.?

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## Public health: control of salmonella and food-born zoonotic agents

The European Parliament adopted a resolution drafted by Marit PAULSEN (ELDR, Sweden) on salmonella and other zoonotic agents. (Please refer to the document dated 17/04/02.) Members made it clear that whilst the purpose of the Regulation is to control salmonella to reduce prevalence, the overriding objective in the long term is to prevent zoonotic agents from entering the human and animal food chain by detecting and controlling them at the earliest stage possible. Regions which have achieved a high level of protection by means of approved control programmes should be allowed, during a transitional period, to impose corresponding requirements in respect of products imported into their territory. Equivalent measures for the control of zoonoses must also be implemented in third countries exporting to the Community at the same time as measures are applied in the Community. Member States on whose territory an inspection is carried out are under a positive duty to provide all necessary assistance to the experts to enable them to carry out their tasks. Finally, the latest date for laboratories to apply quality assurance systems conforming to the current EN/ISO Standard had been brought forward one year to 2004.?

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## Public health: control of salmonella and food-born zoonotic agents

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.?

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## Public health: control of salmonella and food-born zoonotic agents

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.?

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## Public health: control of salmonella and food-born zoonotic agents

The Commission accepts 26 of the 36 amendments proposed by Parliament. These include the following: - the involvement of feed industry together with the food industry in the control measures to control zoonoses; - exempting the production for domestic use from the scope of the Regulation; - requiring Member States, when drawing up national control programmes, to take into account the costs and benefits in order to achieve appropriate distribution of costs; - the FVO will be involved in monitoring the existence of equivalent control programmes in third countries; - broadening certain predefined control measures for salmonella positive flocks of laying hens; - transferring certain criteria from annexes to articles; - consultation of the EFSA is compulsory before adopting decisions concerning specific control measures. Amendments aiming to tighten and add salmonella reduction targets are partly taken into account in the proposal. The target for laying hens is extended to cover all salmonella serotypes with public health significance and a new target for slaughter pigs is added. Proposals to add new targets for calves, other cattle and sheep are rejected. The Commission rejects Parliament's amendment adding an overriding objective to avoid completely the presence of zoonotic agents in the feed and food chain. This objective is impossible to achieve. The Commission also rejected the following: - amendments seeking to add controls of food and other products of plant origin to the scope of the controls; - the addition of an objective to prohibit the use of any antibiotics for preventative purposes or to promote growth in animals. This is outside the scope of the Regulation. - granting transitional additional guarantees for regions with lower prevalence of zoonotic agents; requiring Member States without an approved control programme to be excluded from intra-Community trade in the relevant animals or products; - shortening the time allowed for Member States to submit their reports; - shortening the deadline for laboratories to apply international standards for quality assurance schemes.?

## Public health: control of salmonella and food-born zoonotic agents

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Firstly, it should be stated that the Council welcomes the fact that it has been able to incorporate several of the European Parliament's amendments in its common position and that the Commission accepts these and the other changes to its initial proposal. It hopes that this will permit rapid adoption of the Regulation. The Council, the European Parliament and the Commission agree that the Regulation should establish certain basic principles. In particular, the three Institutions agree that the Regulation should: - provide a flexible framework allowing the progressive extension of control measures to additional animal populations and pathogens; and - in principle, cover all stages of the food chain. As a consequence, the common position adopted by the Council encompasses several 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 : 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. The common position is therefore consistent with the relevant parliamentary amendments. To ensure consistency with the principle of subsidiarity, the common position would leave the control of zoonoses at the level of primary production to national law when such production takes place on a very small scale. The Council considers that it is not appropriate to establish Community control rules to regulate food production activities that have only a slight and localised impact on public health. However, national law would have to achieve the food safety objectives of the Regulation. - Community targets : the Council agrees that: - the Articles ought to contain more detail regarding the setting of Community targets for the reduction of the prevalence of zoonoses and zoonotic agents; - targets ought to be established in respect of all salmonella serotypes with public health significance as soon as is reasonably practicable; - it is appropriate to provide for targets both for breeding and slaughter pigs. However, the Council does not believe that it is yet appropriate to envisage targets for sheep or calves, or for other bovine animals. The common position is therefore consistent with one of the relevant parliamentary amendments and partly consistent with the others. In addition, the common position contains clarification on the scope of Community targets. These would apply to salmonella serotypes with public health significance. Since there are very many salmonella serotypes, and their impact on public health varies greatly, it is necessary to clarify how a list of those salmonella serotypes with public health significance would be drawn up. The common position does this through general criteria contained in the Articles and specific criteria laid down in the Annexes. As regards the timetable for the implementation of Community targets, the common position sets relative dates, linked to the Regulation's entry into force date. This would ensure that, whatever the final date of adoption of the Regulation, there would always be a proper balance between the need to avoid undue delay in implementing the targets and the need to allow sufficient time to make implementation practicable. The common position also provides for an additional six months between the setting of a target the start of the obligation to carry out testing. This would ensure that Member States have time to adapt and to implement national control programmes. The common position provides for the Commission to carry out a cost/benefit analysis before proposing Community targets. To avoid the implementation of the targets from creating undue burdens for primary producers in the first few years of application of the Regulation, it provides for transitional periods. Each target for poultry would, for its first three years of application, apply only to the most prevalent salmonella serotypes (the five most frequent in human salmonellosis as regards breeding hens, and the two most frequent in human salmonellosis in the case of other poultry). The requirement for the Commission to carry out a cost/benefit analysis would not apply during these transitional periods. However, should the Commission carry out such an analysis voluntarily, and if the conclusions justify it, it would be possible to extend the requirements for poultry other than breeding hens to the five most frequent serotypes during the transitional period. - Specific control requirements : the Council agrees that the specific control measures for laying hens should apply to all salmonella serotypes with public health significance. However, it does believe that it would not be practicable to extend the specific control measures for breeding flocks beyond the two most common serotypes in the short term. Consequently, the common position incorporates one of the two relevant parliamentary amendments, but not the other. To be consistent with the approach adopted for Community targets, the common position provides for relative dates for the introduction of specific control measures. It clarifies that detailed rules on how to check compliance with the objective of salmonella-free poultry meat would be laid down through comitology, at the latest one year before the requirement applies. - 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. The common position is therefore consistent with the objective of the relevant parliamentary amendments. - Intra-Community trade : the common position makes clear that the special measures concerning salmonella that currently apply to live animals dispatched to Finland and Sweden would continue to apply after entry into force of the Regulation. Moreover, as the Commission proposed, the Regulation would contain a mechanism making it possible, for a transitional period, to apply additional requirements to trade with other Member States whose national control programmes go beyond the minimum requirements of the Regulation. The same mechanism would allow the requirements concerning Sweden and Finland to be updated. The Council agrees that it is superfluous for this mechanism to cover food, since the Regulation laying down specific hygiene rules for food of animal origin should contain an equivalent mechanism. The Council cannot accept the application of the mechanism to control measures taken to combat zoonotic agents other than salmonella. It believes that it would be disproportionate for failure to have a national control programme approved on time to exclude a Member State from intra-Community trade. Consequently, while it can accept the parliamentary amendment on the first point, it cannot accept those on the two others. - Financial Issues : the Council agrees that national control programmes must have regard to the financial implications for food and feed business operators of control measures. The common position therefore incorporates the relevant parliamentary amendment. In addition, the common position provides for the Commission to report on financial issues and, if appropriate, to make proposals, within three years of entry into force of the Regulation. 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 on the monitoring of zoonoses and zoonotic agents 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. As regards minimum sampling requirements, the common position would maintain an obligation for food business operators to have samples taken and analysed, but would not specify who should meet the costs of these activities. To ensure transparency, Member States would have to include in their national control programmes details of any financial assistance provided to food and feed business operators. - Relationship with other legislation : the common position incorporates amendments to ensure consistency with Regulation 178/2002/EC. In particular, Article 2 now imports the definitions of that Regulation rather than repeating some of them. The common position provides for free-standing definitions of "herd" and "flock", obviating the need for the reader to consult separate acts to understand their meaning. - Consultation of the European Food Safety Authority : the Council agrees that the Commission should consult the European Food Safety Authority (EFSA) before proposing specific control methods. The common position would also require the Commission to consult EFSA before proposing Community targets. The Council does not believe, however, that it is appropriate to make consultation compulsory in all cases. It should be necessary only in cases where the Commission's proposal would have a significant impact on public health. The common position is therefore consistent with the one of the relevant parliamentary amendments but only partially consistent with the other. The common position incorporates parliamentary amendments: - ensuring that the recitals are consistent with the Articles; - enabling 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; - providing for the Commission's Food and Veterinary Office to monitor third countries' control programmes; - on Community controls. The common position does not incorporate amendments: - proposing amendments to the recitals that are not consistent with the Articles or the Annexes; - proposing a political statement rather than a legal obligation; - shortening the deadline for reports; - extending national control programmes to food of plant origin. The Council agrees that laboratories should have to keep pace with any updating of the relevant EN/ISO standard. It considers that it would be impracticable, however, to require compliance with the current standard by 1 January 2004. Instead, the common position would give laboratories 24 months from entry into force of the Regulation to do so. Finally, compared to the Commission's initial proposal, the common position would: - delete the definition of "prevalence", which was superfluous since the Regulation always uses the term in a non-technical manner to describe general objectives; - clarify the procedure for the approval of national control programmes and food and feed business operators' control programmes and the required content of national control programmes; - if necessary to compensate for a different epidemiological situation and to secure equivalent guarantees, make it possible to establish requirements for third countries different from Community targets; - provide for the Regulation to apply six months after its entry into force (that is, at the same time as the repeal of Directive 92/117/EEC); and clarify the minimum sampling requirements and specific control requirements for flocks of breeding hens.?

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## Public health: control of salmonella and food-born zoonotic agents

At the first reading of the European Parliament, the Commission stated that it could accept some or parts of the amendments requested by the European Parliament, but had to reject others. The modified Commission proposal was drafted consequently. The common position does not incorporate European Parliament amendments that were rejected by the Commission. A substantial number of 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. They relate in particular to the scope of the Community targets, the timetable for implementation of the Regulation and the financial aspects. The Council, the European Parliament and the Commission agree that the Regulation should establish certain basic principles. In particular, the three Institutions agree that the Regulation should: - provide a flexible framework allowing the progressive extension of control measures to additional animal populations and pathogens; and - in principle, cover all stages of the food chain. The Commission states that it will not propose any measure that would reduce the guarantees granted to Finland and Sweden upon their accession to the Community. It also declares that targets for stages of the food chain after primary production will generally be laid down through comitology pursuant to Article 4 of the proposed Regulation on the hygiene of foodstuffs. These will supplement the targets for table eggs and poultry meat contained in the proposed Regulation on the control of zoonoses (which may themselves be modified or supplemented through comitology). Lastly, the Commission declares that the envisaged order of the Community targets for pigs may be reversed if the evaluation of the available evidence indicates that this would be more appropriate.?

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## Public health: control of salmonella and food-born zoonotic agents

The committee adopted the report by Marit PAULSEN (ELDR, S) amending the Council's common position under the 2nd reading of the codecision procedure. While welcoming the fact that the common position had incorporated the bulk of Parliament's 1st reading amendments, MEPs felt that three new aspects were unacceptable and needed modifying: - the reference to a "favourable cost/benefit analysis" (on the basis of which the Commission would propose Community targets where appropriate) should be deleted, on the grounds that public health and the illness and suffering of individuals cannot reasonably be assessed in strictly economic terms; - the Community target should not be based on "a weighted average of the data for the last three years for which data are available", as this would mean using old data to deal with a current situation; - the Community target should not be restricted to a maximum of five serotypes during a transitional period. The committee also proposed that, for the purposes of determining the salmonella serotypes with public health significance to which Community targets will apply, invasive and/or antibiotic-resistant serotypes should also be taken into account, as should the presence of the serotype in animal feed (i.e. not just in relevant animal populations).?

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## Public health: control of salmonella and food-born zoonotic agents

The European Parliament adopted a resolution drafted by Marit PAULSEN (ELDR, Sweden) and made a few amendments to the common position. (Please refer to the document dated 21/05/03).?

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## Public health: control of salmonella and food-born zoonotic agents

The amendments accepted by the Commission concern the following: - the outcome of cost/benefit analyses to be provided by the Commission when defining Community targets is acceptable, as it avoids misinterpretation of the word "favourable" mentioned in the common position. The Commission clarified its intention in a declaration (see in Annex). The amendment does not hamper the principle of preliminary cost/benefit analyses when defining Community targets pursuant to the Regulation; - the scope of the Community targets during transitional periods is acceptable. The first part of the amendment concerning the use of historical data to define salmonella serotypes composing the target on breeding flocks of *Gallus gallus* during the transitional period, provides more flexibility than the text in the common position to use available data in the most appropriate way. The Commission clarified its intention in a declaration. The second part of the amendment can be accepted because it is consistent with the general principle established in Article 4, paragraph 4, to define targets on the basis of cost/benefit analyses; - the specific criteria to determine salmonella serotypes with public health significance, are acceptable. Another amendment makes reference to feed, which is consistent with the need to consider feed as a source of infection of animal populations. National control programmes have to cover the feed industry. Another amendment adds to the list of criteria, whether serotypes have a profile making them particularly hazardous for humans. The Commission can support that amendment. It should be noted that there were no amendments rejected by the Commission. The Commission has included two declarations in the framework of the second reading. These are as follows: - In relation to Article 4(4)(c): The Commission declares that, in relation to Article 4(4)(c), it will take due account of the results of cost/benefit analyses and other legitimate factors. It will not propose targets that would lead to disproportionate costs in comparison to the expected benefits of Community action. - In relation to Article 4(5), subpara. 2 : The Commission declares that, in relation to the use of data on human

salmonellosis collected through EC monitoring systems to define salmonella serotypes with public health significance, it will take account both of historical data and of recent trends, as most appropriate to the circumstances.?

## Public health: control of salmonella and food-born zoonotic agents

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**PURPOSE** : ensure that proper and effective measures are taken to detect and to control salmonella and other zoonotic agents at all relevant stages of production, processing and distribution, particularly at the level of primary production, including in feed, in order to reduce their prevalence and the risk they pose to public health. **LEGISLATIVE ACT** : Regulation 2160/2003/EC of the European Parliament and of the Council on the control of salmonella and other specified food-borne zoonotic agents. **CONTENT** : the "zoonoses package" revises and replaces Directive 92/117/EEC of the Council concerning measures for protection against specified zoonoses and specific zoonotic agents in animals and products of animal origin in order to prevent outbreaks of food-borne infections and intoxications. The Regulation on control of salmonella and other specified food-borne zoonotic agents provides for effective measures to be progressively implemented to control specified food-borne zoonotic agents, primarily in specified animal populations but possibly also at other stages of the food chain where appropriate, in order to reduce the risk these agents pose to public health. The primary aim is to control salmonella with public health significance in critical categories of animals. The objectives of the Regulation are to: - progressively set Community targets for the reduction of the prevalence of specified zoonotic agents and implement related national control programmes; - provide for a procedure by which the use of specific control measures may be subject to particular requirements or restrictions; - provide for rules for trade and imports of live animals and hatching eggs to be set; - set specific requirements concerning animal populations covered by control measures and, where appropriate, after transitional periods have elapsed. This Regulation shall cover: a) the adoption of targets for the reduction of the prevalence of specified zoonoses in animal populations: i) at the level of primary production; and ii) where appropriate for the zoonosis or zoonotic agent concerned, at other stages of the food chain, including in food and feed; b) the approval of specific control programmes established by Member States and food and feed business operators; c) the adoption of specific rules concerning certain control methods applied in the reduction of the prevalence of zoonoses and zoonotic agents; d) the adoption of rules concerning intra-Community trade and imports from third countries of certain animals and products thereof. **ENTRY INTO FORCE** : 12/12/2003. It shall apply as from 12/06/2004.?

## Public health: control of salmonella and food-born zoonotic agents

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**LEGISLATIVE ACT**: Commission Regulation 1003/2005/EC implementing Regulation 2160/2003/EC as regards a Community target for the reduction of the prevalence of certain salmonella serotypes in breeding flocks of *Gallus gallus* and amending Regulation 2160/2003/EC.

**CONTENT**: The purpose of Regulation 2160/2003/EC is to ensure that proper and effective measures are taken to detect and control salmonella and other zoonotic agents at all relevant stages of production, processing and distribution, particularly at the level of primary production, in order to reduce their prevalence and the risk they pose to public health.

Under that Regulation a Community target is to be established for the reduction of the prevalence of all salmonella serotypes with public health significance in breeding flocks of *Gallus gallus* at the level of primary production.

The Community target for the reduction of *Salmonella enteritidis*, *Salmonella hadar*, *Salmonella infantis*, *Salmonella typhimurium* and *Salmonella virchow* in breeding flocks of *Gallus gallus* shall be a reduction of the maximum percentage of adult breeding flocks comprising at least 250 birds remaining positive to 1 % or less by 31 December 2009.

However, for Member States with fewer than 100 breeding flocks, not more than one adult breeding flock shall remain positive.

The testing scheme to verify the achievement of the Community target is set out in the Annex to the Regulation.

**ENTRY INTO FORCE**: 01/07/2005.

## Public health: control of salmonella and food-born zoonotic agents

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**LEGISLATIVE ACT**: Commission Regulation 1091/2005/EC implementing Regulation 2160/2003/EC of the European Parliament and of the Council as regards requirements for the use of specific control methods in the framework of the national programmes for the control of salmonella.

**CONTENT**: Under Regulation 2160/2003/EC, it may be decided that specific control methods are not to be used as part of national control programmes established by Member States to achieve the Community targets set up in accordance with that Regulation. Also, under Regulation 2160/2003/EC it may be decided that specific control methods may or shall be applied for the reduction of prevalence of zoonoses and zoonotic agents at the stage of the primary production of animals and other stages in the food chain, and rules may be adopted concerning the conditions for the use of such methods.

The Commission consulted EFSA on the use of antimicrobials and on the use of vaccines for the control of salmonella in poultry. Following that request, EFSA issued two separate opinions on those issues on 21 October 2004. In its opinion on the use of antimicrobials for the control of salmonella in poultry, EFSA recommended that the use of antimicrobials should be discouraged due to public health risks associated with development, selection and spread of resistance. The use of antimicrobials should be subject to formally defined conditions that would ensure protection of public health, and must be fully justified in advance and recorded by the competent authority.

As regards breeding flocks, while the opinion acknowledged the potential risk of dissemination of residual *Salmonella* spp., including dissemination of any selected resistant strains through the production pyramid, it recognised that valuable genetic material may be salvaged from infected breeding flocks through the use of antimicrobials. The opinion concluded also that most generally and for all types of poultry, on the rare occasions when *Salmonella* spp. causes clinical infections, antimicrobials may be useful in reducing morbidity and mortality.

This Commission Regulation thus lays down that antimicrobials shall not be used as a specific method to control salmonella in breeding flocks of *Gallus gallus* in the framework of national control programmes adopted pursuant to Article 6 of Regulation 2160/2003/EC, except in the following exceptional circumstances:

- animals presenting salmonella infection with clinical signs in a way likely to cause undue suffering to the animals; the infected breeding flocks treated with antimicrobials shall still be considered infected with salmonella, and appropriate measures shall be taken to reduce as much as possible the risk of spreading salmonella through the rest of the breeding pyramid;

- salvaging of valuable genetic material, including 'elite flocks', flocks from endangered breeds, and flocks kept for research purposes, in order to establish new salmonella-free flocks; chicks born from hatching eggs collected from treated animals shall be subject to fortnightly sampling during the rearing phase, with a scheme aiming to detect 1 % prevalence of relevant salmonella with a 95 % confidence limit;

- authorisation given by the competent authority on a case by case basis for purposes other than salmonella control in a flock suspect of salmonella infection, in particular following detection of salmonella at the hatchery or at the holding; however, Member States may decide to allow treatment without prior authorisation in emergency situations, subject to reporting the treatment immediately to the competent authority.

The use of antimicrobials shall be subject to authorization and supervision of the competent authority and shall be based wherever possible on the results of bacteriological sampling and of susceptibility testing.

Live salmonella vaccines for which the manufacturer does not provide an appropriate method to distinguish bacteriologically wild-type strains of salmonella from vaccine strains shall not be used in the framework of national control programmes adopted pursuant to Article 6 of Regulation 2160/2003/EC.

ENTRY INTO FORCE: 02/08/2005.

DATE OF APPLICATION: 01/01/2007.

## Public health: control of salmonella and food-born zoonotic agents

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ACT: Commission Regulation 1168/2006/EC implementing Regulation 2160/2003/EC as regards a Community target for the reduction of the prevalence of certain salmonella serotypes in laying hens of Gallus gallus and amending Regulation 1003/2005/EC.

CONTENT: to recall, Regulation 2160/2003/EC establishes Community targets for the reduction of salmonella serotypes in laying hens of Gallus gallus. The Regulation also sets Community targets that include a numerical expression of the maximum percentage of epidemiological units remaining positive and/or the minimum percentage of reduction in the number of epidemiological units remaining positive, the maximum time limit within which the target must be achieved and the definition of the testing schemes necessary to verify achievement of the target.

In 2005, the Community adopted Regulation 1003/2005/EC concerning the setting of Community targets for the reduction of certain salmonella serotypes in breeding flocks of Gallus gallus. However, since the adoption of the Regulation alternative analysis methods have been developed and validated. Further, salmonella strains detected in breeding flocks need to be stored for future phagotyping and anti-microbial susceptibility testing.

The purpose of this Regulation, therefore, is to amend Regulation 1003/2005/EC in accordance with the opinion of the 'Standing Committee on Food and Animal Health.' Accordingly, the Community target for the reduction of Salmonella enteritidis and Salmonella typhimurium in adult laying hens of Gallus gallus is as follows:

- An annual minimum percentage of reduction of positive flocks of adult laying hens equal to at least:
  - (i) 10 % if the prevalence in the preceding year was less than 10 %;
  - (ii) 20 % if the prevalence in the preceding year was between 10 and 19 %;
  - (iii) 30 % if the prevalence in the preceding year was between 20 and 39 %;
  - (iv) 40 % if the prevalence in the preceding year was 40 % or more;

or;

- A reduction of the maximum percentage to 2 % or less. However, for Member States with less than 50 flocks of adult laying hens, not more than one adult flock may remain positive.

The first target needs to be achieved by 2008 based on monitoring begun at the beginning of that year. Achievements will be based on the result of evaluations taken in three consecutive years.

ENTRY INTO FORCE : 04/08/2006. The Regulation shall apply from 01/08/2006.

## Public health: control of salmonella and food-born zoonotic agents

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ACT: Commission Regulation 1177/2006/EC implementing Regulation 2160/2003/EC of the European Parliament and of the Council as regards requirements for the use of specific control methods in the framework of the national programmes for the control of salmonella in poultry.

CONTENT: following a request from the Commission, the EFSA issued an opinion in which it stated that the use of antimicrobials for the control of salmonella in poultry should be discouraged due to public health risks associated with development, selection and the spread of resistance. As a result of the EFSA opinion, this Regulation lays down certain rules for the use of antimicrobials and vaccines within the framework of the national control programmes.

The Regulation states that the use of antimicrobials shall not be used as a specific method to control salmonella in poultry. A number of derogations are listed ' for example, poultry presenting salmonella infection with clinical signs of the disease or the salvaging of valuable genetic material in breeding flocks in order to establish new salmonella-free flocks.

The Regulation also states:



- Live salmonella vaccines should not be used where there is no provision for an appropriate method to distinguish bacteriologically wild-type strains of salmonella from vaccine strains.
- Live salmonella vaccines should not be used in laying hens during production.
- Vaccination against Salmonella enteritidis should be applied during rearing (at the least) to all laying hens at the latest from 1 January 2008.

ENTRY INTO FORCE: 22/08/2006.

## Public health: control of salmonella and food-borne zoonotic agents

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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 humans 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 853/2004) 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).