Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of salmonella and other specified food-borne zoonotic agents

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on the control of salmonella and other specified food-borne zoonotic agents

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 152(4)(b) thereof,

Having regard to the proposal from the Commission[(1)],

Having regard to the opinion of the European Economic and Social Committee[(2)],

After consulting the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty[(3)],

Whereas:

(1) Live animals and food of animal origin appear on the list in Annex I to the Treaty. Livestock farming and the placing on the market of food of animal origin constitute an important source of income for farmers. The implementation of veterinary measures aimed at raising the level of public and animal health in the Community assists the rational development of the farming sector.

(2) The protection of human health against diseases and infections transmissible directly or indirectly between animals and humans (zoonoses) is of paramount importance.

(3) Zoonoses transmissible through food may cause human suffering, as well as economic losses to food production and the food industry.

(4) Zoonoses transmitted through sources other than food, especially from wild animal and pet animal populations, are also a matter of concern.

(5) Zoonoses present at the level of primary production must be adequately controlled to ensure that the objectives of this Regulation are achieved. However, in the case of primary production leading to the direct supply of small quantities of primary products, by the food business operator producing them, to the final consumer or to local shops, it is appropriate to protect public health through national law. In this case there is a close relationship between the producer and the consumer. Such production should not make a significant contribution to the average prevalence of zoonoses in animal populations in the Community as a whole. The general requirements for sampling and analysis may not be practical or appropriate for producers with very small numbers of animals who may be located in regions suffering from special geographical constraints.

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(6) Council Directive 92/117/EEC of 17 December 1992 concerning measures for protection against specified zoonoses and specified zoonotic agents in animals and products of animal origin in order to prevent outbreaks of food-borne infections and intoxications[(4)] provided for the establishment of monitoring systems for certain zoonoses and controls on salmonella in certain poultry flocks.

(7) That Directive required Member States to submit to the Commission the national measures that they had taken to achieve the objectives of the Directive and to draw up plans for monitoring salmonella in poultry. However, Council Directive 97/22/EC[(5)] amending Directive 92/117/EEC suspended the requirement pending the review provided for in Article 15a of Directive 92/117/EEC.

(8) Several Member States have already submitted their plans for the monitoring of salmonella, which the Commission has approved. Moreover, all Member States were required, with effect from 1 January 1998, to fulfil the minimum measures laid down for salmonella in Annex III, Section I, to Directive 92/117/EEC, and to establish rules specifying the measures to be taken to avoid the introduction of salmonella on to a farm.

(9) Those minimum measures focused on monitoring and controlling salmonella in breeding flocks of the species *Gallus gallus*. When serotypes *Salmonella enteritidis* or *Salmonella typhimurium* were detected and confirmed in samples taken, Directive 92/117/EEC laid down specific measures to control the infection.

(10) Other Community legislation provides for the monitoring and control of certain zoonoses in animal populations. In particular Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine[(6)] deals with bovine tuberculosis and bovine brucellosis. Council Directive 91/68/EEC of 28 January 1991 on animal health conditions governing intra-Community trade in ovine and caprine animals[(7)] deals with ovine and caprine brucellosis. This Regulation should not create any unnecessary duplication of these existing requirements.

(11) Moreover, future Community legislation on food hygiene should cover specific elements necessary for the prevention, control and monitoring of zoonoses and zoonotic agents and include specific requirements for the microbiological quality of food.

(12) Directive 92/117/EEC provided for the collection of data on the occurrence of zoonoses and zoonotic agents in feedingstuffs, animals, food and humans. That data collection system, although not harmonised and therefore not allowing comparison between Member States, does provide a basis for evaluating the current situation concerning zoonoses and zoonotic agents in the Community.

(13) The results of the data collection system show that certain zoonotic agents, namely *Salmonella* spp. and *Campylobacter* spp., cause the majority of cases of zoonoses in humans. There seems to be a decreasing trend of human cases of salmonellosis, in particular due to *Salmonella enteritidis* and *Salmonella typhimurium*, thus reflecting the success of related control measures taken in the Community. Nevertheless, it is assumed that many cases remain unreported and therefore the data collected do not necessarily give the full picture of the situation.

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(14) In its opinion on zoonoses adopted on 12 April 2000, the Scientific Committee on Veterinary Measures relating to Public Health considered that the measures in place at that time to control food-borne zoonotic infections were insufficient. It further considered that the epidemiological data that Member States were collecting were incomplete and not fully comparable. As a consequence, the Committee recommended improved monitoring arrangements and identified risk management options.

(15) It is therefore necessary to improve the existing control systems for specific zoonotic agents. Simultaneously, the rules laid down in Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC[(8)] will replace the monitoring and data collection systems established by Directive 92/117/EEC.

(16) In principle, controls should cover the whole food chain, from farm to table.

(17) The rules governing such controls should generally be those laid down under Community legislation on feedingstuffs, animal health and food hygiene.

(18) However, for certain zoonoses and zoonotic agents it is necessary to lay down specific requirements for controls.

(19) Those specific requirements should be based on targets for the reduction of the prevalence of zoonoses and zoonotic agents.

(20) The targets should be established for zoonoses and zoonotic agents in animal populations taking account, in particular, of their frequency and epidemiological trends in animal and human populations, feed and food, their gravity for humans, their potential economic consequences, scientific advice and the existence of appropriate measures to reduce their prevalence. Targets may be established in respect of other parts of the food chain, where necessary.

(21) To ensure the achievement of the targets in good time, Member States should set up specific control programmes, which the Community should approve.

(22) The main responsibility for the safety of food should lie with food and feed business operators. Member States should, therefore, encourage the creation of business-wide control programmes.

(23) Within their control programmes, Member States and food and feed business operators may wish to use specific control methods. However, certain methods may not be acceptable, in particular if they hamper the achievement of the target in general, interfere specifically with necessary testing systems or give rise to potential threats to public health. Appropriate procedures should therefore be laid down enabling the Community to decide that certain control methods should not be used as part of control programmes.

(24) Control methods may also exist or be developed which, as such, do not fall under any specific Community legislation on product approval but would help to achieve the

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targets for the reduction of the prevalence of specified zoonoses and zoonotic agents. It should, therefore, be possible to approve the use of such methods at Community level.

(25) It will be essential to ensure that restocking of animals takes place from flocks or herds that have been subject to controls in accordance with the requirements of this Regulation. When a specific control programme is in force, the results of testing should be forwarded to purchasers of animals. To that end, specific requirements should be added to the corresponding Community legislation on intra-Community trade and imports from third countries, in particular as regards consignments of live animals and hatching eggs. Directive 64/432/EEC, Council Directive 72/462/EEC of 12 December 1972 on health and veterinary inspection problems upon importation of bovine animals and swine and fresh meat from third countries[(9)] and Council Directive 90/539/EEC of 15 October 1990 on animal health conditions governing intra-Community trade in, and imports from third countries of, poultry and hatching eggs[(10)] should be amended accordingly.

(26) The adoption of this Regulation should not affect the additional guarantees agreed for Finland and Sweden on their accession to the Community and confirmed by Commission Decisions 94/968/EC[(11)], 95/50/EC[(12)], 95/160/EC[(13)], 95/161/EC[(14)], 95/168/EC[(15)] and by Council Decisions 95/409/EC[(16)], 95/410/EC[(17)] and 95/411/EC[(18)]. This Regulation should provide a procedure for the granting, for a transitional period, of guarantees to any Member State that has an approved national control programme exceeding the minimum Community requirements in relation to salmonella. The results of tests on live animals and hatching eggs traded with such a Member State should meet the criteria laid down in its national control programme. Future Community legislation on hygiene rules for food of animal origin should provide a similar procedure in respect of meat and table eggs.

(27) Third countries exporting to the Community must implement equivalent measures for the control of zoonoses at the same time as measures are applied in the Community.

(28) As regards control of salmonella, available information tends to show that poultry products are a major source of human salmonellosis. Control measures should, therefore, be applied to production of those products, thus extending the measures initiated under Directive 92/117/EEC. As regards the production of table eggs, it is important to establish specific measures concerning the placing on the market of products originating from flocks that have not been tested free of relevant salmonella. As regards poultry meat, the aim is to place on the market poultry meat with reasonable assurance that it is free from relevant salmonella. A transitional period is necessary for food business operators to adapt to the measures envisaged, which may be adapted further in particular in the light of scientific risk assessment.

(29) It is appropriate to designate national and Community reference laboratories to give guidance and assistance on matters falling within the scope of this Regulation.

(30) To ensure the uniform application of this Regulation, provision should be made for the organisation of Community audits and inspections in accordance with other Community legislation in this field.

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(31) Appropriate procedures should be laid down for amending certain provisions of this Regulation to take account of technical and scientific progress and for the adoption of implementing and transitional measures.

(32) To take account of technical and scientific progress, close and effective cooperation should be ensured between the Commission and the Member States within the Standing Committee set up by Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority, and laying down procedures in matters of food safety[(19)].

(33) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission[(20)],

HAVE ADOPTED THIS REGULATION:

CHAPTER I

INTRODUCTORY PROVISIONS

Article 1

Subject matter and scope

1 The purpose of this Regulation is to 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.

2 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.

3 This Regulation shall not apply to primary production:

a for private domestic use; or

b leading to the direct supply, by the producer, of small quantities of primary products to the final consumer or to local retail establishments directly supplying the primary products to the final consumer.