# COMMISSION REGULATION (EC) No 1091/2005

## of 12 July 2005

## implementing Regulation (EC) No 2160/2003 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

**(Text with EEA relevance)**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to 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 [1] and, in particular Article 8(1) thereof,

Whereas:

(1) Under Regulation (EC) No 2160/2003, 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.

(2) Also, under Regulation (EC) No 2160/2003 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.

(3) Pursuant to Article 15 of Regulation (EC) No 2160/2003, the Commission is to consult the European Food Safety Authority (EFSA) before proposing rules on specific control methods.

(4) 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.

(5) 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.

(6) 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.

(7) Therefore, on the basis of the opinion of EFSA, it is appropriate to provide that antimicrobials should not be used as part of national control programmes to be adopted pursuant to Article 6 of Regulation (EC) No 2160/2003, other than in the exceptional circumstances referred to by EFSA in its opinion.

(8) In any circumstances, only veterinary medicinal products authorised in accordance with Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products [2], or Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency [3], should be used. Anti-microbial veterinary medicinal products are referred to as anti-microbials in this Regulation.

(9) It is generally recognised that the basis for successful control of salmonlla infections in poultry farms are good farming and hygienic practices as well as testing and removal of positive flocks from production.

(10) In its opinion on the use of vaccines for the control of salmonella in poultry, EFSA concludes that vaccination of poultry is regarded as an additional measure to increase the resistance of birds against salmonella exposure and decrease the shedding.

[1] OJ L 325, 12.12.2003, p. 1.

[2] OJ L 311, 28.11.2001, p. 1. Directive as last amended by Directive 2004/28/EC (OJ L 136, 30.4.2004, p. 58).

[3] OJ L 136, 30.4.2004, p. 1.

(11) In its conclusions, EFSA also states in particular that provided that the detection methods are able to differentiate the vaccine strains from wild strains, both inactivated and live vaccines can be safely used throughout the life of the birds except during the withdrawal period before slaughter.

(12) Therefore, on the basis of the opinion of EFSA, it is appropriate to provide that live vaccines should not be used as part of national control programmes to be adopted pursuant to Article 6 of Regulation (EC) No 2160/2003, if the manufacturer does not provide an appropriate method to distinguish bacteriologically wild-type strains of salmonella from vaccine strains.

(13) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

*Article 1*

**Use of antimicrobials**

1. 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 (EC) No 2160/2003, except in the circumstances established in paragraph 2.

2. By way of derogation from paragraph 1, and subject to the conditions specified in points (a), (b) and (c) and in paragraph 3, antimicrobials authorised in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004 may be used in the following exceptional circumstances:

(a) 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;

(b) 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;

(c) 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.

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

*Article 2*

**Use of vaccines**

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 (EC) No 2160/2003.

*Article 3*

**Entry into force**

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 January 2007.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 12 July 2005.

*For the Commission*
Markos KYPRIANOU
*Member of the Commission*