Commission Regulation (EC) No 1177/2006 of 1 August 2006 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 in poultry (Text with EEA relevance)

COMMISSION REGULATION (EC) No 1177/2006

of 1 August 2006

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 in poultry

(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) Regulation (EC) No 2160/2003 lays down rules for the detection and control of salmonella in poultry. Pursuant to Article 8(1)(d) of 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) Pursuant to Article 8(1)(a) and (b) of Regulation (EC) No 2160/2003 it may be decided that specific control methods are or may 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 the EFSA on the use of antimicrobials and vaccines for the control of salmonella in poultry. Following that consultation, the 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, the 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

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protection of public health, and must be fully justified in advance and recorded by the competent authority.

(6) Therefore, on the basis of the opinion of the 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 the EFSA in its opinion.

(7) 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.

(8) Antimicrobial veterinary medicinal products are referred to as antimicrobials in this Regulation. Products which are authorised as feed additives in accordance with Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition[(4)] are however also considered as antimicrobials. They should be excluded from the scope of this Regulation because the use of these additives may be a tool to limit salmonella infection by the feed while they are not associated with the development, selection and spread of resistance.

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

(10) The EFSA in its opinion also stated in particular that provided that the detection methods are able to differentiate the vaccine strains from wild strains, both currently available inactivated and live vaccines can be safely used throughout the life of the birds, except during the withdrawal period before slaughter and, with regard to live vaccines, in laying hens during production. Vaccination of layers is considered useful as a measure to reduce shedding and egg contamination, when the purpose is to reduce high prevalences. *Salmonella enteritidis* is the most important cause of outbreaks in humans by the consumption of eggs.

(11) Therefore, on the basis of the opinion of the EFSA, it is appropriate to provide that currently available 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, in laying hens during production. Live vaccines should not be used if the manufacturer does not provide an appropriate method to distinguish bacteriologically wild-type strains of salmonella from vaccine strains.

(12) Based on the current scientific evidence, the use of live or inactivated vaccines against *Salmonella enteritidis* should be mandatory in Member States with a high prevalence in order to improve public health protection. The prevalence of *Salmonella enteritidis* demonstrated during a baseline study in accordance with Commission Decision 2004/665/EC[(5)] and in the frame of the testing schemes in accordance with

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Article 4(2)(d) of Regulation (EC) No 2160/2003, should be used as a threshold for mandatory vaccination.

(13) As regards breeding flocks, Commission Regulation (EC) No 1091/2005 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[(6)], lays down provisions on the use of antimicrobials and vaccines as part of national control programmes for salmonella in breeding flocks of *Gallus gallus*.

(14) For the sake of clarity, it is appropriate to repeal and replace Regulation (EC) No 1091/2005 by this Regulation.

(15) 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

This Regulation lays down certain rules for the use of antimicrobials and vaccines in the framework of the national control programmes adopted pursuant to Article 6 of Regulation (EC) No 2160/2003 (national control programmes).

Article 2

Use of antimicrobials

1 Antimicrobials shall not be used as a specific method to control salmonella in poultry.

2 By way of derogation from paragraph 1, and subject to the conditions specified in points (a), (b) and (c), and in paragraph 3 of this Article, antimicrobials authorised in accordance with Article 5 of Directive 2001/82/EC or Article 3 of Regulation 726/2004/EC may be used in the following exceptional circumstances:

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

b salvaging of valuable genetic material in breeding flocks in order to establish new salmonella-free flocks, including ‘elite flocks’, flocks from endangered breeds, and flocks kept for research purposes; chicks born from hatching eggs collected from poultry treated with antimicrobials 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 the epidemiological investigation of a food-borne outbreak or the 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 taking samples by an approved veterinarian as defined in point (g) of Article 2 of Regulation (EC) No 854/2004[(7)] and reporting the treatment immediately to the