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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 29.10.2008
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Proposal for a

COUNCIL REGULATION

implementing Regulation (EC) No 853/2004 of the European Parliament and of the Council as regards the use of antimicrobial substances to remove surface contamination from poultry carcasses

(presented by the Commission)

EXPLANATORY MEMORANDUM

Regulation (EC) No 853/2004 lays down specific rules on the hygiene of food of animal origin for food business operators. It provides that food business operators are not to use any substance other than water to remove surface contamination from products of animal origin, unless the use of the substance has been approved in accordance with that Regulation. It provides that the use of approved substances is not to affect the obligations of food business operators to comply with the requirements of that Regulation.

In October 1998 and April 2003, different scientific opinions were issued by the Scientific Committee on Veterinary measures relating to Public Health (SCVPH) and concluded that the use of antimicrobial substances can contribute to the decrease of pathogens in the poultry provided those substances are used in the framework of an integrated control system of the food chain. .

In the framework of the EC-USA Veterinary Agreement, the USA submitted files concerning the use of four antimicrobial substances on poultry carcasses. These files were transmitted to the European Food Safety Authority (EFSA), which adopted an opinion in December 2005. EFSA concluded that the use of these substances (chlorine dioxide, acidified sodium chlorite, trisodium phosphate and peroxyacids) in the described conditions does not present any risk to public health and that the use of antimicrobial solutions does not replace the need for good hygienic practices during processing of poultry carcasses, particularly during handling. In a second opinion in December 2005, EFSA nevertheless pointed out that the information provided on peroxyacids indicated limited effectiveness, requiring specific conditions of use to be defined.

On 6 March 2008, EFSA in its scientific opinion on the Assessment of the possible effect of the four antimicrobial treatment substances on the emergence of antimicrobial resistance concludes that there are currently no published data to conclude in whatever way on the occurrence of acquired reduced susceptibility to these substances when applied on poultry carcasses and to resistance to therapeutic antimicrobials.

Finally on 31 March 2008 , the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) and the Scientific Committee on Health and Environmental Risks (SCHER) in their joint opinion on environmental impact and effect on antimicrobial resistance of the four substances used for the removal of microbial surface contamination of poultry carcasses conclude that there is not enough information available for producing comprehensive quantitative assessments that there is an environmental concern about the possibility to disseminate or select more resistant strains and, finally, that a low environmental risk has been estimated in relation to the potential residues in the carcasses.

Against this background, a draft Commission Regulation approving the use of four substances to remove surface contamination from poultry carcasses and setting down the conditions under which the substances may be used was submitted to the Standing Committee of the Food Chain and Animal Health, on 2 June 2008, for vote. The Committee delivered an opinion against the proposal: 26 Member States voted against and one Member State abstained.

Consequently, pursuant to Article 3(2) of Regulation (EC) No 853/2004 and in accordance with Article 5 of Council Decision 1999/468/EC modified by Council Decision 2006/512/EC, the Commission is submitting to the Council a proposal relating to the measures to be taken, the Council having three months in which to act by a qualified majority, and is informing the Parliament.

This proposal has no financial implications for the Community budget.

Proposal for a

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implementing Regulation (EC) No 853/2004 of the European Parliament and of the Council as regards the use of antimicrobial substances to remove surface contamination from poultry carcasses

(Text with EEA relevance)

THE COUNCIL OF THE EUROPEAN UNION

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 853/2004 of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin¹, and in particular Article 3(2) thereof,

Whereas:

- (1) Regulation (EC) No 853/2004 lays down specific rules on the hygiene of food of animal origin for food business operators. It provides that food business operators are not to use any substance other than water to remove surface contamination from products of animal origin, unless the use of such substance has been approved in accordance with that Regulation.
- (2) Therefore it is appropriate to approve the use of certain antimicrobial substances for the removal of surface contamination from poultry carcasses.
- (3) Council Directive 91/271/EEC of 21 May 1991 concerning urban waste water treatment² lays down rules regarding the treatment and discharge of waste water from certain industrial sectors.
- (4) Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC)³ lays down minimum requirements for the protection of workers at the workplace from risks to their safety or health arising due to the presence of chemical agents.
- (5) 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

¹ OJ L 139, 30.4.2004, p. 55; corrected version (OJ L 226, 25.6.2004, p. 22). Regulation as last amended by Commission Regulation (EC) No 1243/2007 (OJ L 281, 25.10.2007, p. 8).

² OJ L 135, 30.5.1991, p. 40. Directive as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

³ OJ L 131, 5.5.1998, p. 11. Directive as amended by Directive 2007/30/EC of the European Parliament and of the Council (OJ L 165, 27.6.2007, p. 21).

zoonotic agents⁴ provides for measures to be taken to detect and control salmonella and other zoonotic agents at all relevant stages of production, processing and distribution. It provides for national control programmes for the detection of zoonoses and zoonotic agents at the primary production stage targeted at specific pathogens.

- (6) Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules⁵ lays down general rules for the performance of official controls to verify compliance with rules concerning preventing, eliminating or reducing to acceptable levels risks to humans and animals.
- (7) Those acts provide for certain hygiene and other obligations on food business operators and controls to be carried out by the competent authority. However, it is necessary to provide for additional conditions and requirements on the part of the food business operators and controls by the competent authority in addition to those already provided for in the existing Community legislation, for the use of antimicrobial substances for the removal of surface contamination from poultry carcasses.
- (8) A high level of protection of human health is assured in the pursuit of Community policies. Measures adopted by the Community governing food and feed must be based on an appropriate assessment of the possible risks for human and animal health and must, taking into account existing scientific evidence, maintain, or if scientifically justified increase, the level of protection of human and animal health ensured in the Community. It is impossible, however, to consider the complete elimination of any risk as a realistic objective for the risk management decision in the present matter. It is the role and responsibility for the risk manager to decide the acceptable level of risk, taking into account all the elements present in a scientific risk assessment.
- (9) In addition, a high level of protection of the environment is ensured in the pursuit of Community policies, both by acts of environmental policy itself and by the integration of environmental policy requirements into the definition and implementation of other Community policies and activities.
- (10) The Scientific Committee on Veterinary Measures relating to Public Health (“SCVPH”) issued a report on 30 October 1998 on the “benefits and limitations of antimicrobial treatments for poultry carcasses” and recommended that before any decontamination compound or decontamination technique is authorised for use, it should be fully assessed.
- (11) The SCVPH also issued an opinion on 14 and 15 April 2003 on “the evaluation of antimicrobial treatments for poultry carcasses” and concluded that decontamination can constitute a useful element in further reducing the number of pathogens provided an integrated control strategy is applied throughout the entire food chain, including hygienic measures applied at primary production, during transport and in the slaughter and processing plant.

⁴ OJ L 325, 12.12.2003, p. 1. Regulation as last amended by Commission Regulation (EC) No 1237/2007 (OJ L 280, 24.10.2007, p. 5).

⁵ OJ L 165, 30.4.2004, p. 1; corrected version (OJ L 191, 28.5.2004, p. 1). Regulation as last amended by Council Regulation (EC) No 301/2008 (OJ L 97, 9.4.2008, p. 85).

- (12) The European Food Safety Authority (“EFSA”) adopted a scientific opinion on 6 December 2005, in which it concluded that the treatment of poultry carcasses with chlorine dioxide, acidified sodium chlorite, trisodium phosphate or peroxyacids does not constitute a safety concern. It also noted that by comparison to dipping and immersion in repeatedly used water in chiller baths, spraying reduces the exposure to residues and animal by-products that might arise from the application of antimicrobial substances.
- (13) The toxicological effects of the application of more than one antimicrobial substance used simultaneously or consecutively for the removal of surface contamination of food of animal origin has not been properly evaluated. Therefore, combinations of several antimicrobial substances should not be used.
- (14) The EFSA adopted a scientific opinion on 6 March 2008 "on the assessment of possible effect of the four antimicrobial treatment substances on the emergence of antimicrobial resistance." It concluded that there are currently no published data to conclude that the application of the four substances referred to in its opinion of 6 December 2005 will lead to the occurrence of acquired reduced susceptibility to these substances and to resistance to therapeutic antimicrobials. These findings lead the EFSA to encourage further research on the likelihood of the emergence of such susceptibility to these types of substances, and the possibility of their resistance to therapeutic antibiotics and other antimicrobial agents.
- (15) The Scientific Committee on Health and Environmental Risks (SCHER) and the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) adopted a joint scientific opinion on 18 March 2008 and 2 April 2008 on the environmental impact and effect on the antimicrobial resistance of the four substances used for the removal of microbial surface contamination of poultry carcasses in which they stated that "there is currently insufficient knowledge on the potential negative effects of using different biocides." In response to the mandate of the Commission on the four substances, they concluded that there is not enough information available for producing comprehensive quantitative assessments. There is an environmental concern about the possibility to disseminate or select more resistant strains and in relation to the potential residues in the poultry carcasses. However, both the SCHER and the SCENHIR consider that the environmental risk is low.
- (16) The Commission, in its role as risk manager responsible for the establishment of the acceptable level of risk to public and animal health and the environment, considers that the risk of a possible antimicrobial resistance effect and a possible environmental impact of the four antimicrobial substances cannot be excluded. Consequently, very strict conditions and requirements regarding the use of these four substances, in particular regarding the time of exposure, the concentration of the substances and the limitation of the application to only one substance, should be laid down in order to further reduce any risks.
- (17) Several antimicrobial substances that are used to remove surface contamination from poultry carcasses could pose a risk to the aquatic environment, the health of staff working in waste water systems and the operation and performance of sewerage systems and/or waste water treatment plants. The use of antimicrobial substances containing chlorine could lead to the formation of chloroorganic compounds, several of which are persistent, bioaccumulable or carcinogenic. Phosphorus compounds are

also one of the sources of the eutrophication of European regional seas, leading to mass growth algae and other undesirable disturbance of the aquatic environment. Accordingly, provision should make for appropriate controls for the disposal of such substances.

- (18) The use of antimicrobial substances, other than potable water, on poultry carcasses should be indicated on the labelling of poultry carcasses, and on cuts and meat preparations derived from such poultry carcasses, in order to inform the consumer. Accordingly, it is appropriate to provide for such labelling requirements in this Regulation.
- (19) Substances used for the removal of surface contamination from poultry carcasses and not for conservation purposes do not affect the definition of 'fresh meat' in point 1.10 of Annex I to Regulation (EC) No 853/2004.
- (20) However, this Regulation should apply only after the definition of poultrymeat set out in point 1 of Part B.II of Annex XIV to Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation)⁶ has been amended. That amendment would permit the placing on the market and the marketing of meat which has been treated with antimicrobial substances as poultrymeat.
- (21) It is appropriate to approve the use of chlorine dioxide, acidified sodium chlorite, trisodium phosphate and peroxyacids for the removal of surface contamination from poultry carcasses pending further scientific data to be provided by the food business operators in Member States regarding the use of such substances. That information should cover the possible environmental impact and the possible emergence of antimicrobial resistance. Food business operators in Third Countries are invited to submit the data to the latter. These data will be the basis for the review of the authorisation as well as of the conditions of use of these substances.
- (22) The Standing Committee on the Food Chain and Animal Health has delivered an unfavourable opinion on the Commission proposed measures and the measures provided for in this Regulation must therefore be adopted by the Council ,

HAS ADOPTED THIS REGULATION:

Article 1
Approved substances

The antimicrobial substances listed in the Annex are approved for the removal of surface contamination from poultry carcasses ('approved substances').

⁶ OJ L 299, 16.11.2007, p. 1. Regulation as last amended by Council Regulation (EC) No 248/2008 (OJ L 76, 19.3.2008, p. 6).

Article 2
Obligations of food business operators regarding the use of approved substances

Food business operators shall only apply the approved substances to whole poultry carcasses, and not to parts of carcasses or poultry cuts.

They shall only apply the approved substances to poultry carcasses under the conditions set out in the Annex and in compliance with the following requirements:

- (a) there must be no simultaneous or consecutive application of more than one approved substance to the poultry carcass;
- (b) where an approved substance is used more than once during the production process, the total contact time must not exceed the periods set out in points 2, 3 and 4 of the Annex.
- (c) where an approved substance is used in a pre-chiller or chiller tank, the solution containing that substance must be replaced at regular intervals in order to maintain the prescribed concentration of the approved substance;
- (d) the poultry carcass must be rinsed with potable water, including an inside rinsing of the eviscerated poultry carcass, at an appropriate point in the production process following the application of the approved substance, to ensure that the substance is intentionally removed to such an extent that it does not have a technological effect in the final product;
- (e) the efficacy of the rinsing, which must ensure that no residues of the approved substance or possible derivatives thereof remain in the final product, must be scientifically demonstrated by an appropriate permanent monitoring.
- (f) the application of the approved substance and rinsing must be performed in the slaughter room before the poultry carcasses enter the chilling or refrigerating room;

Article 3
Data collection obligations of food business operators

1. Food business operators shall collect data for the following research purposes:
 - (a) the likelihood of the emergence of acquired reduced susceptibility to the approved substances and resistance to therapeutic antimicrobials;
 - (b) the environmental impact of the disposal of the used solutions of the approved substances and leaching water;
 - (c) the possibility that resistant strains are disseminated or selected in the waste water.
2. Food business operators shall make the data provided for in paragraph 1 available to the competent authority as soon as the Commission will define the technical specifications.

Article 4
Labelling

Where an approved substance has been used for the removal of surface contamination from poultry carcasses, the food business operator shall label the poultry carcasses and any poultry cuts and poultrymeat preparations derived therefrom, in a conspicuous and clearly legible and indelible manner, as either:

- (a) treated with antimicrobial substances; or
- (b) decontaminated by chemicals.

Article 5
Waste water

1. Food business operators shall comply with the following waste water effluent quality standards where the use of approved substances is linked to the discharge of waste water to an urban collection and treatment system or to the discharge of industrial waste water into waters following treatment:
 - (a) effluent quality for discharges into urban collection and treatment systems:

total chlorine (expressed as Cl ₂):	0.4 mg/l
chloroorganic compounds, expressed as absorbable organic halogenated compounds (AOX)	1.0 mg/l

(b) effluent quality for discharges into surface waters:	
total chlorine (expressed as Cl ₂):	0.4 mg/l
total phosphorus (expressed as P):	2.0 mg/l
chloroorganic compounds, expressed as absorbable organic halogenated compounds (AOX)	0.1 mg/l

2. Food business operators shall monitor compliance with the effluent quality standards provided for in paragraph 1 at least once a month based on flow-proportional 24 hours sampling.

The monitoring of effluent quality shall be based on International Standards ISO 7393-1:1985/2001, ISO 7393-2:1985, ISO 7393-3:1990, ISO 6878:2004 and ISO 9562:2004. However, the competent authority may permit the use of other methods if it can be demonstrated that the results obtained are equivalent to those obtained through the ISO methods.

Article 6 *Official controls*

1. Where an approved substance is used for the removal of surface contamination from poultry carcasses, the competent authority:
 - (a) shall increase the frequency of and/or extend the duration of official controls, in particular the official controls provided for in Article 10 of Regulation (EC) No 882/2004, with special emphasis on the obligations of food business operators as provided for in Article 2 of this Regulation;
 - (b) may, on a case-by-case basis, lay down additional conditions concerning the use of that substance.
2. The competent authority shall carry out official controls on the monitoring performed by food business operators as provided for in Article 5(2).

Article 7 *Data collection obligations of the competent authority*

The competent authority shall transmit the data provided for in Article 3 to the Commission every six months from the date of application of this Regulation.

Article 8
Entry into force, review, and application

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

It shall apply from the date of application of the Council Regulation amending the definition of poultry meat in point 1 of Part B.II of Annex XIV to Council Regulation (EC) No 1234/2007.

Within 2 years from the date of application, the Commission shall review this Regulation in the light of further scientific data regarding the use of the substances listed in the Annex and, if necessary, will propose any necessary adaptations to the authorisation.

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

Done at Brussels,

For the Council
The President

ANNEX

List of approved substances and the conditions for their application

(as provided for in Article 2)

1. Chlorine dioxide:
 - (a) at a maximum concentration of 3 mg/kg of residual chlorine dioxide in water at those points of the production process where the approved substance is used;
 - (b) in the case of continuous, counter-flow, immersion chilling, the contact time must be proportionate to the size of the poultry carcasses and must be assessed in connection with the concentration of chlorine dioxide used.
2. Acidified sodium chlorite:
 - (a) in poultry processing waters applied as pre-chiller or chiller solutions at concentrations between 50 and 150 mg/kg of sodium chlorite combined with an acid permitted for food use that achieves a pH between 2.8 – 3.2 in the solution; the solution shall be applied as an immersion dip for up to 5 to 8 seconds in total;
 - (b) in poultry processing waters applied as spray solutions at concentrations between 500 and 1200 mg/kg of sodium chlorite combined with an acid permitted for food use that achieves a pH between 2.3 – 2.9 in the solution; the solution shall be applied as a spray for up to 15 seconds in total.
3. Trisodium phosphate:

in poultry processing waters at concentrations from 80 g/kg to 120 g/kg. The solution shall be applied by the dipping or spraying of poultry carcasses, which have not been cooled, for up to 15 seconds in total.
4. Peroxyacids:

in poultry processing waters a mixture of peroxyacetic acid, octanoic acid, acetic acid, hydrogen peroxide, peroxyoctanoic acid and 1-hydroxyethylidene-1, 1-diphosphonic acid (HEDP) may be used at a maximum concentration of 220 mg/kg peroxyacetic acid, 110 mg/kg hydrogen peroxide and 13 mg/kg HEDP for up to 15 seconds in total when applied as a spray or dip.