EUROPEAN COMMISSION

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COMMISSION REGULATION (EU) No .../..

of XXX

concerning the use of lactic acid to reduce microbiological surface contamination on bovine carcases

SANCO/11970/2011 rev. 3

(Text with EEA relevance)

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COMMISSION REGULATION (EU) No .../..

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concerning the use of lactic acid to reduce microbiological surface contamination on bovine carcases

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 853/2004 of 29 April 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 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs² lays down general rules for food business operators on the hygiene of foodstuffs, taking particular account of the principle concerning the general implementation of procedures based on hazard analysis and critical control point (HACCP).
- (2) 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 potable water to remove surface contamination from products of animal origin, unless use of the substance has been approved in accordance with that Regulation.
- (3) In addition, Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs³ lays down the microbiological criteria for certain microorganisms and the implementing rules to be complied with by food business operators when implementing the general and specific hygiene measures referred to in Regulation (EC) No 852/2004. It provides that food business operators are to ensure that foodstuffs are to comply with those microbiological criteria.
- (4) On 14 December 2010, the Commission received an application for approval of the use of lactic acid to reduce surface contamination of boyine carcases and meat.

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OJ L 139, 30.4.2004, p. 55.

² OJ L 139, 30.4.2004, p. 1.

OJ L 338, 22.12.2005, p. 1.

- (5) On 26 July 2011, the European Food Safety Authority ("EFSA") adopted a Scientific Opinion on the evaluation of the safety and efficacy of lactic acid for the removal of microbial surface contamination from beef carcases, cuts and trimmings⁴.
- (6) In its Opinion, EFSA concludes that the treatments using lactic acid for decontamination of bovine carcases, cuts and trimmings are of no safety concern, provided that the substance used complies with Union specifications for food additives. In addition, EFSA concludes that treatments with lactic acid provide a significant reduction of microbiological contamination compared to no treatment or to treatment with potable water and that it is unlikely that such treatments would contribute to the development of microbial resistance.
- (7) EFSA recommends that food business operators validate the antimicrobial efficacy of such treatments under their specific processing conditions and verify lactic acid concentration, temperature of application and other factors affecting its efficacy as a decontaminating agent.
- (8) According to the EFSA Opinion, the residual amount absorbed in the beef meat from lactic acid treatment will not be higher than 190 mg/kg. Such amount is considered residual compared to the active amount necessary for the purpose of reducing microbial surface contamination. Furthermore, it does not have any technological effect in the final product. In addition, the residual amount of lactic acid used for reducing microbial surface contamination is negligible compared to the amount of lactic acid naturally present in beef and it is of no safety concern. In certain meat preparations, which fall under the category of fresh meat as defined in Regulation (EC) No 853/2004, lactic acid is authorised as food additive for the purpose of preservation. For this purpose levels of 20.000 mg/kg are currently used. Therefore, the use of lactic acid for the purpose of reducing microbial surface contamination is clearly distinct from its use as a food additive and its use for the reduction of surface contamination in bovine carcases -and not for conservation purposes- does not affect the status of meat as defined in Regulation (EC) No 853/2004.
- (9) In view of the EFSA Opinion, taking into account that lactic acid can provide a significant reduction of possible microbiological contamination, it is appropriate to approve its use to reduce surface contamination. Such use should however be subjected to certain conditions. Its use should be limited to the use on carcases or half carcases or quarters at the level of the slaughterhouse and applied after the health marking.
- (10) The use of lactic acid to reduce microbiological surface contamination on bovine carcases or half carcases or quarters must not affect the food business operator's duty to comply with the requirements of Union legislation on food hygiene, as laid down in Regulations (EC) No 852/2004, No 853/2004 and No 2073/2005. Such use should be integrated into good hygienic practices and HACCP-based systems and in no way it should be considered as a substitution for good hygienic slaughtering practices and operating procedures or as an alternative to comply with the requirements of those Regulations.

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⁴ EFSA Journal 2011;9(7):2317.

(11) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee of the Food Chain and Animal Health, and neither the European Parliament nor the Council has opposed them.

HAS ADOPTED THIS REGULATION:

Article 1

Food business operators may use lactic acid to reduce microbiological surface contamination on bovine carcases or half carcases or quarters at the level of the slaughterhouse in compliance with the conditions set out in the Annex to this Regulation

Article 2

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

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

Done at Brussels, [...]

For the Commission
The President
[...]

ANNEX

Part I – Conditions of use of lactic acid to reduce microbiological surface contamination of bovine carcases or half carcases or quarters at the level of the slaughterhouse

1. Lactic acid solutions must only be prepared from lactic acid following the specifications of Commission Directive 2008/84/EC laying down specific purity criteria⁵.

2. Lactic acid solutions must:

- (a) only be applied on entire carcases or half-carcases or quarters of meat from domestic bovine animals (including *Bubalus* and *Bison* species) at the level of the slaughterhouse after post mortem inspection is completed and the meat has been declared fit for human consumption;
- (b) only be applied either by spraying or misting using from 2% to 5% lactic acid solution in potable water at temperatures of up to a maximum of 55°C;
- (c) be applied under controlled and verifiable conditions integrated in a HACCP-based management system including, at least, the criteria set out in Part II.
- 3. Lactic acid solutions must not be applied to carcases with visible faecal contamination.
- 4. The application of lactic acid solutions must not result in any irreversible physical modification of the meat.

Part II – Minimum HACCP criteria and control parameters

- 1. Sampling of carcases for the purposes of assessing compliance with microbiological criteria within the meaning of Regulation (EC) No 2073/2005 must be carried out before the application of lactic acid solutions on the carcases or half-carcases or quarters.
- 2. Lactic acid concentration during treatment must be, as part of the HACCP plan, verified by periodic monitoring, documented and recorded.
- 3. The temperature of the lactic acid solution during treatment must, as part of the HACCP plan, be continuously monitored by instrumental measurements, documented and recorded.

Part III - Food chain information

Food business operators operating slaughterhouses in which lactic acid solutions are used to reduce microbial surface contamination of entire carcases or half-carcases or quarters must inform the food business operator receiving the treated carcases or half-carcases or quarters of such use. This information should be documented.

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⁵ OJ L 253, 20.9.2008, p. 1.