



Brussels, 3.10.2012
COM(2012) 578 final

2012/0280 (NLE)

Proposal for a

COUNCIL REGULATION

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

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

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.

On 14 December 2010, the Commission received an application for approval of the use of lactic acid to reduce surface contamination of bovine carcasses and meat.

On 26 July 2011, the European Food Safety Authority (EFSA) adopted a favourable opinion on the evaluation of the safety and efficacy of lactic acid for decontamination purposes. The Commission therefore proposed measures concerning the use of lactic acid to reduce surface contamination on bovine carcasses.

2. RESULTS OF CONSULTATIONS WITH THE INTERESTED PARTIES AND IMPACT ASSESSMENTS

A draft Commission Regulation approving the use of lactic acid to reduce surface contamination on bovine carcasses was submitted to the Standing Committee of the Food Chain and Animal Health, on 21 September 2012, for an opinion. The Committee did not deliver an opinion on the draft Commission Regulation, as a qualified majority was not reached neither for nor against the proposed measures.

Consequently, pursuant to Article 3(2) of Regulation (EC) No 853/2004 and in accordance with Article 5a of Council Decision 1999/468/EC, the Commission is submitting to the Council and the Parliament a draft Council Regulation relating to the measures to be taken, the Council having two months in which to give its position following which the Parliament would also have an additional two months to give its position. In the absence of an opinion of the Council, the Regulation is sent back to the Commission and the Commission has the legal obligation to adopt the measures.

No impact assessment was foreseen for this implementing Regulation.

3. LEGAL ELEMENTS OF THE PROPOSAL

Following the positive EFSA Scientific Opinion and taking into account that lactic acid can provide a significant reduction of possible microbiological contamination, it is deemed appropriate to approve its use to reduce surface contamination of bovine carcasses. Such use should however be subjected to certain conditions (concentration, temperature, etc.) as reported in Part I of the Annex to this Regulation.

The use of lactic acid for surface decontamination should be limited to the use on carcasses or half carcasses or quarters at the level of the slaughterhouse and it should be integrated into good hygienic practices and HACCP-based systems. Furthermore, its use 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- and should in no way be considered as a substitution for good hygienic slaughtering practices and operating procedures.

Proposal for a

COUNCIL REGULATION

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

(Text with EEA relevance)

THE COUNCIL OF THE EUROPEAN UNION,

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

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 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 bovine carcasses and meat.

¹ OJ L 139, 30.4.2004, p. 55.

² OJ L 139, 30.4.2004, p. 1.

³ 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 carcasses, cuts and trimmings⁴.
- (6) In its Opinion, EFSA concludes that the treatments using lactic acid for decontamination 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. The EFSA Opinion also concluded that there are no negative implications resulting from this use of lactic acid on the environment.
- (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, lactic acid salts are authorised as food additives for the purpose of preservation. For this purpose, levels of 20.000 mg/kg are commonly 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.
- (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 carcasses or half carcasses or quarters at the level of the slaughterhouse and it should be integrated into good hygienic practices and HACCP-based systems.
- (10) Commission Regulation (EU) No 231/2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council⁵ lays down specifications for food additives relating, in particular, to origin, purity criteria and any other necessary information.
- (11) In accordance with the EFSA Opinion, lactic acid used to reduce surface contamination in bovine carcasses should comply with the specifications for lactic acid laid down in Union legislation. Consequently, where lactic acid is used to reduce microbiological surface contamination pursuant to this Regulation, it is appropriate that such lactic acid complies with the specifications laid down in Regulation (EU) No 231/2012.

⁴ EFSA Journal 2011;9(7):2317.

⁵ OJ L 83, 22.3.2012, p. 1.

- (12) The use of lactic acid to reduce microbiological surface contamination on bovine carcasses or half carcasses 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 and should in no way 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.
- (13) The Standing Committee on the Food Chain and Animal Health has not delivered an opinion within the time limit laid down by its Chairman. The measures provided for in this Regulation should therefore be adopted by the Council,

HAS ADOPTED THIS REGULATION:

Article 1

Food business operators may use lactic acid to reduce microbiological surface contamination on bovine carcasses or half carcasses 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 Council
The President

ANNEX

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

1. Lactic acid solutions must only be prepared from lactic acid which complies with the specifications set out in Regulation (EU) No 231/2012.
2. Lactic acid solutions must:
 - (a) only be applied on entire carcasses or half-carcasses or quarters of meat from domestic bovine animals (including *Bubalus* and *Bison* species) at the level of the slaughterhouse;
 - (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 carcasses 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 carcasses 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 carcasses or half-carcasses 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 – Information on the treatment

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