
DRAFT COMMISSION REGULATION CONCERNING THE USE OF LACTIC ACID TO REDUCE MICROBIOLOGICAL SURFACE CONTAMINATION ON BOVINE CARCASSES

Report by Alison Gleadle, Director, Food Safety

1 SUMMARY

1.1 The European Commission has initiated discussion on a proposal to authorise the use of lactic acid as a decontaminating treatment in beef production. The FSA has previously held the view that in principle it does not oppose the use of decontamination treatments in raw meat production provided their safety is proven and they are not used as a substitute for good hygienic practice. The timing of the vote on this draft Commission proposal is currently unclear, but may be in 2012. The Board is asked to agree the FSA advice on food safety and other interests of consumers in relation to the proposal. This advice will inform Ministerial decisions on the position the UK Government should take in the forthcoming negotiations.

1.2 The Board is asked to:

- **Confirm** the principle that the FSA does not oppose the use of decontamination treatments in raw meat production provided their safety is proven and they are not used as a substitute for good hygienic practice.
- **Note** that EFSA has concluded that the use of lactic acid as a decontaminating treatment in beef production is safe and effective.
- **Note** the potential food safety benefits of the draft proposal.
- **Agree** the FSA advice to Ministers should be:

Recommend supporting the proposal in principle as an intervention of public health benefit, subject to safeguards to ensure that the use of lactic acid in raw beef production “should be integrated into good hygienic practices and HACCP-based systems”, as worded in the current draft proposal.

- **Agree** that labelling of products treated with this substance is not appropriate and would have ensuing enforcement issues.

2 INTRODUCTION

2.1 Regulation (EC) No 853/2004 provides that substances other than potable water (or clean water, where permitted) cannot be used to remove surface contamination from foods of animal origin unless the use of the substance has been approved. At present no approvals have been granted. In the USA a range of substances are permitted to be used to reduce surface contamination. Meat produced using these substances is not allowed to be imported into the EU. The USA views this as a trade barrier, arguing that controlled use of such

post slaughter decontamination treatments is both safe and effective in reducing the number of pathogens on the surface of the meat.

- 2.2 In December 2010 the US Department of Agriculture (USDA) submitted a dossier to the European Union for evaluation and approval of the use of lactic acid for the decontamination of beef carcasses and meat. EFSA published its favourable Scientific Opinion in July 2011 and presented it to Member States at the Standing Committee on the Food Chain and Animal Health (SCoFCAH) on 15 September 2011. The Scientific Opinion, which considered the dossier in terms of safety and efficacy, concludes that the treatment would be of no safety concern provided that the substance used complies with EU specifications for lactic acid as a food additive. The EFSA Opinion is summarised in Annexe 1.
- 2.3 The Scientific Opinion is the first step in the EU legislative process which would culminate in a vote at SCoFCAH to authorise, or not, the use of lactic acid as a decontaminant on beef carcasses. The Commission has drafted a proposal on the use of lactic acid to reduce microbiological surface contamination on bovine carcasses, attached at Annexe 2. This will go through EU Working Groups and may be modified during these discussions. The timing of any vote on the proposal is uncertain. If authorised, this would apply equally to beef carcasses produced in the EU and those imported into the EU from Third countries.
- 2.4 Lactic acid¹ is a natural and common component of many foods. It is formed by natural fermentation in products such as cheese, yogurt, soy sauce, sourdough, meat products and pickled vegetables. It has a natural antimicrobial function which is the basis of the preservation achieved in fermented foods. Lactic acid found naturally in animals and humans has many functions, the most important of which is related to the supply of energy in muscle tissue.
- 2.5 A previous Commission proposal on the use of four chlorine-based antimicrobial treatments to reduce surface decontamination from poultry carcasses was considered by the FSA in July 2008 (Annexe 3). The Executive recommended to the Board then that in principle it should not oppose the use of decontamination treatments in raw meat production provided their safety is proven and they are not used as a substitute for good hygienic practice. The 2008 proposal, however, had uncertainties in relation to the environmental impact and the potential for antimicrobial resistance which the FSA Board felt were not fully addressed. The FSA Board advised Ministers to abstain from voting on the proposal at that time. In relation to lactic acid, the EFSA Scientific Opinion specifically addresses environmental considerations, concluding that the concentration of lactic acid just before entering the wastewater treatment system is negligible. For this reason, EFSA considered an environmental risk assessment to be unnecessary.

¹ Although the name suggests it, commercial lactic acid is not derived from milk. Dairy based lactic acid is not manufactured /sold on a commercial scale. Lactic acid can be produced in a natural manner by the fermentation of beet /cane sugar or glucose, or produced synthetically

- **Potential emergence of reduced susceptibility to biocides or resistance to therapeutic antimicrobials:** Although data was not submitted, the Opinion concludes that development of resistance is unlikely⁶.
- **Risk related to the release of the processing plant effluents:** The Opinion concludes that an environmental risk assessment was not necessary as the concentration of lactic acid entering the waste water treatment system is considered negligible.

Commission Proposal

- 4.2 The proposal (Annexe 2) was discussed at SCoFCAH on 17 October 2011. Members States' views were mixed. There were concerns that authorisation of lactic acid use on beef may open the door for approval of less acceptable antimicrobial treatments (e.g. chlorine-based decontaminants), issues of consumer acceptance and confidence, concerns with the lack of labelling provisions in the proposal (see paragraph 5.3), some confusion whether lactic acid use should be approved as a food additive⁷, and concerns over conditions of use so that it would not become a substitute for good hygienic practice.
- 4.3 There is some concern that the use of decontaminating treatments may be viewed by the public as 'cleaning up dirty meat'. There is a perceived risk that Food Business Operators could see the use of decontaminating treatments as a replacement for good hygiene practice. This same argument was used to prevent pasteurisation of milk, with the result that several thousand people died unnecessarily in the UK between World War I and World War II. It is estimated that 65,000 people died from milk-borne tuberculosis between 1912 and 1937⁸.
- 4.4 The FSA recognises a whole food chain approach to food safety and that decontaminating treatments are only one of several measures that could potentially be used. As such we would insist that their use does not lead to lowering of standards during the whole production chain, i.e. that they are not used as a substitute for good husbandry and hygienic practices on farm, in the slaughterhouse and in any further processing. This principle is already explicitly clear in the European Commission's proposed legislation: "Such use should be integrated into good hygienic practices and HACCP-based systems and in no way should it 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".
- 4.5 The proposal stipulates that sampling to demonstrate compliance with microbiological criteria laid down in Regulation EC No. 2073/2005 must be undertaken prior to treatment with lactic acid. The industry has argued that this would limit the value of applying the treatment. The Commission however has advised that the intention would be to take samples to verify compliance with

⁶ It was concluded that the development of enzymatic resistance to therapeutic antimicrobials as a result of exposure to lactic acid is unlikely. Considering the extensive natural presence of lactic acid in fermented food, the possibility of mutational change resulting in the development of resistance to therapeutic antimicrobials is also unlikely to be a significant issue. There is some evidence that repeated exposure to lactic acid can select for reduced susceptibility to the substance. Under good hygienic practices (GHP), this possibility is not considered a significant issue

⁷ Lactic acid is already an approved additive, but not for meat

⁸ Gillespie I A, Adak G K, O'Brien S J and Bolton F J; *Epidemiology and Infection* 2003; 130; 461-468

these criteria prior to using the treatment. This would contribute to data demonstrating food safety management systems based on HACCP principles are under control.

5 STAKEHOLDER AND CONSUMER ENGAGEMENT

- 5.1 Limited information is available on consumer acceptance of decontamination treatments. The FSA has carried out some preliminary consumer research to explore this issue in the context of *Campylobacter* on chickens, but more needs to be done. The FSA funded Citizen Forums concluded that consumers supported the use of lactic acid in poultry processing compared to other processing interventions as it was considered more natural than chlorine washes or irradiation. The FSA is funding further research on consumer attitudes to decontamination treatments on meat carcasses, in particular lactic acid, which will be completed mid 2012.
- 5.2 The FSA has written to industry and consumer representatives inviting their views on the draft Commission proposal and its scope. Initial views from UK stakeholders are mixed and summarised in Annexe 4. There are stakeholder concerns that:
- Authorisation could lead to a drop in hygiene standards
 - Lactic acid washing should only take place post health marking⁹
 - The use of lactic acid should remain permissive and not mandatory
 - Any meat treated with lactic acid must be clearly labelled as such.
- 5.3 **Labelling:** The draft proposal does not provide for the labelling of products. The Commission's reasons for not including a provision for labelling arise from the EFSA Scientific Opinion that the treatment would be of no safety concern provided that the substance used complies with EU specifications for food additives. Very small quantities of lactic acid are left on the meat when used as specified in the proposal, and it cannot be differentiated from natural lactic acid which could lead to difficulties with enforcement. In addition, if products treated with lactic acid were labelled then there would be the need to address the labelling of products made from treated meat later in the food chain, making it difficult to determine at what point labelling would no longer be required.

6 DEVOLUTION

- 6.1 The Food Advisory Committees of Northern Ireland, Scotland and Wales have been consulted on the proposal. Defra and the devolved administrations, and the UK Chief Medical Officers, have been invited to comment on the proposal. The Advisory Committee on the Microbiological Safety of Food has been made aware of the proposal and the scientific risk assessment carried out by EFSA.

7 IMPACT

- 7.1 The potential financial implications of the proposal for the UK have yet to be assessed. The direct financial implications to industry are likely to be minimal as the proposal is to authorise the use of lactic acid rather than impose its use.

⁹ The UK raised this issue with the Commission and it is now a provision in the latest version of the proposal

- 7.2 If the use of lactic acid is authorised for use on beef carcasses, a subsequent approval for its use on poultry carcasses is more likely to be achieved and this could have a significant impact on foodborne disease. The use of lactic acid to reduce *Campylobacter* levels on chicken carcasses, as part of wider activity on farm and in the slaughterhouse, could contribute to between a 15% and 30% reduction in human cases¹⁰.
- 7.3 Wider approval of decontaminating treatments could potentially have an impact on the UK market by increasing the amount of imported meat to the UK, i.e. meat currently not permitted because of the widespread use of surface decontamination treatments, most notably from the USA.
- 7.4 Conversely, should the EU not approve the use of lactic acid on beef then this could indicate an unwillingness to allow the use of such treatments. This could potentially impact on UK trade.

8 LEGAL IMPLICATIONS

- 8.1 The legal basis for authorisation of the use of lactic acid on beef would be Regulation (EC) No 853/2004, laying down specific hygiene rules for food of animal origin (in particular Article 3(2) and the procedure referred to in Article 12(3)). If a proposal to authorise the use of lactic acid on beef carcasses were to be adopted it would allow its use on beef produced in the EU and beef imported into the EU from Third countries.

9 RESOURCE IMPLICATIONS

- 9.1 There are minimal additional resource implications to projected spend on the strategic plan outcome to reduce foodborne disease.

10 RISK IMPLICATIONS

- 10.1 The approval of lactic acid as a decontaminant, initially for beef and possibly for all meat in the future, has the potential to significantly reduce risk to foodborne disease (see paragraph on Impact). Approval for use on beef could be a step towards subsequent approval for use in poultry meat production.
- 10.2 Both approval and lack of approval could have potential trade implications (see Impact above). This is an area for consideration by other Departments.

11 SUSTAINABILITY ISSUES

- 11.1 The EFSA Scientific Opinion has considered the environmental impact and concluded that the concentration of lactic acid entering the processing plant waste water treatment system is considered as negligible. Lactic acid is a biodegradable, naturally occurring substance, and has been assessed as safe for use as a food additive.

¹⁰ <http://www.food.gov.uk/multimedia/pdfs/campytarget.pdf>

11.2 The Opinion concludes that there are no environmental risks associated with use of lactic acid for this purpose. It is for Defra and devolved environment departments to consider this conclusion and advise the Government accordingly.

12 CONCLUSION AND RECOMMENDATIONS

12.1 Independent scientists advising EFSA have concluded that there are no safety concerns regarding the use of lactic acid on beef carcasses.

12.2 The draft Commission proposal recognises that the control of zoonotic agents in primary production and during processing through good hygienic practice and application of HACCP based principles is of utmost importance. The use of decontaminating treatments must complement rather than replace an integrated control strategy. The UK could insist on no relaxation of good hygienic practice and the principles of HACCP in beef production, and seek provisions in the proposal to safeguard these measures, e.g. insist that lactic acid use should only take place post health marking. Subject to these conditions, the proposal would not raise any food safety concerns.

12.3 It is appropriate that the draft Commission proposal does not provide for the labelling of treated products as only very small quantities of lactic acid are left on the meat when used as specified in the proposal. In addition, it cannot be differentiated from natural lactic acid. Labelling of food products that contain treated meat as an ingredient would also be difficult to enforce.

12.4 The Board is asked to:

- **Confirm** the principle that the FSA does not oppose the use of decontamination treatments in raw meat production provided their safety is proven and they are not used as a substitute for good hygienic practice.
- **Note** that EFSA has concluded that the use of lactic acid as a decontaminating treatment in beef production is safe and effective.
- **Note** the potential food safety benefits of the draft proposal.
- **Agree** the FSA advice to Ministers should be:

Recommend supporting the proposal in principle as an intervention of public health benefit, subject to safeguards to ensure that the use of lactic acid in raw beef production “should be integrated into good hygienic practices and HACCP-based systems”, as worded in the current draft proposal.

- **Agree** that labelling of products treated with this substance is not appropriate and would have ensuing enforcement issues.

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SCIENTIFIC OPINION

Scientific Opinion on the evaluation of the safety and efficacy of lactic acid for the removal of microbial surface contamination of beef carcasses, cuts and trimmings¹

EFSA Panel on Biological Hazards (BIOHAZ)^{2, 4}
EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF)^{3, 4}
European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

Studies evaluating the safety and efficacy of lactic acid treatment for decontamination of beef carcasses, cuts and trimmings were assessed. Treatments considered consisted of using 2 % to 5 % lactic acid solutions at temperatures of up to 55 °C applied either by spraying or misting. It is concluded that these treatments will be of no safety concern provided the substance used complies with the European Union specifications for food additives. A total of 25 papers of the 52 submitted were selected as meeting certain criteria and were included in the assessment of the antimicrobial efficacy of lactic acid. No studies applying water rinsing of lactic acid after treatment of beef were submitted, and therefore, this issue was not addressed. As the studies described in the selected papers used a wide range of experimental designs, the assessment did not attempt to differentiate efficacy based on factors such as lactic acid concentration and temperature, that might influence efficacy. It was concluded that, although variable, microbial reductions achieved by lactic acid treatment of beef are generally significant compared to untreated or water treated controls. Development of enzymatic resistance to therapeutic antimicrobials as a result of exposure to lactic acid and the possibility of mutational changes resulting in the development of resistance to therapeutic antimicrobials are unlikely. An environmental risk assessment was not carried out as the lactic acid concentration before entering the wastewater treatment system is considered as negligible. It is recommended that, according to HACCP principles, during use, business operators verify lactic acid concentration, temperature of application and other factors affecting its efficacy as a decontaminating agent and validate the antimicrobial efficacy under their specific processing conditions.

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¹ On request from the European Commission, Question No EFSA-Q-2011-00032, adopted on 7 July 2011 by the BIOHAZ Panel and No EFSA-Q-2011-00081, adopted on 18 May 2011 by the CEF Panel.

² BIOHAZ Panel members: Olivier Andreoletti, Herbert Budka, Sava Buncic, John D Collins, John Griffin, Tine Hald, Arie Havelaar, James Hope, Günter Klein, Kostas Koutsoumanis, James McLauchlin, Christine Müller-Graf, Christophe Nguyen-The, Birgit Nørrung, Luisa Peixe, Miguel Prieto Maradona, Antonia Ricci, John Sofos, John Threlfall, Ivar Vågsholm and Emmanuel Vanopdenbosch. Correspondence: biohaz@efsa.europa.eu

³ CEF Panel members: Arturo Anadon, Mona-Lise Binderup, Wilfried Bursch, Laurence Castle, Riccardo Crebelli, Karl-Heinz Engel, Roland Franz, Nathalie Gontard, Thomas Haertle, Trine Husøy, Klaus-Dieter Jany, Catherine Leclercq, Jean-Claude Lhuguenot, Wim Mennes, Maria Rosaria Milana, Karla Pfaff, Kettel Svensson, Fidel Toldra, Rosemary Waring and Dettlef Wölflé. Correspondence: CEF-unit@efsa.europa.eu

⁴ Acknowledgement: The Panels wish to thank the members of the Working Group on the evaluation of the safety and efficacy of lactic acid for the removal of microbial surface contamination of beef carcasses, cuts and trimmings: Arie Havelaar, Birgit Nørrung, John Sofos, John Threlfall and Fidel Toldrá for the preparatory work on this scientific opinion and EFSA staff: Winy Messens for the support provided to this scientific opinion.

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KEY WORDS

Decontamination, beef, lactic acid, efficacy, toxicological safety assessment, antimicrobial resistance, environmental impact

SUMMARY

Following a request from the European Commission, the Panel on Biological Hazards (BIOHAZ Panel) and the Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF Panel) were asked by the European Food Safety Authority (EFSA) to deliver a Scientific Opinion on an application dossier submitted by the U.S. Department of Agriculture (USDA) for the approval of lactic acid for uses to reduce microbial contamination of beef hides, carcasses, cuts and trimmings. More specifically, the approval was sought for treatments using lactic acid solution concentrations from 2 % to 5 % (wt/wt) at temperatures of up to 55 °C applied either by spraying or misting.

The Commission asked EFSA to issue a Scientific Opinion on the assessment of the safety and efficacy of lactic acid when used to reduce microbial surface contamination on beef hides, carcasses, cuts and trimmings. Specifically, the task was to consider the toxicological safety of the substance, its antimicrobial efficacy, the potential emergence of reduced microbial susceptibility to biocides and/or resistance to therapeutic antimicrobials linked to the use of the substance, and any risk related to the release of the slaughterhouse and/or processing plant effluents containing the substance into the environment. The assessment was based on the document “Guidelines on the submission of data for the evaluation of the safety and efficacy of substances for the removal of microbial surface contamination of foods of animal origin intended for human consumption” published by EFSA⁵.

Concerning the human toxicological safety of the substance, it was concluded that the treatments, as described, would be of no safety concern provided that the substance used complies with the European Union specifications for food additives. This was based on the expected low level of exposure deriving from the use of lactic acid on carcasses, cuts and trimmings, and the fact that it is an endogenous substance.

A total of 25, of the 52 papers submitted by the applicant, were selected based on identified criteria and were used in the assessment of the efficacy of lactic acid as a decontaminating agent for beef hides, carcasses, cuts and trimmings. Since no studies were submitted for the evaluation of the lactic acid efficacy when its application was followed by water rinsing, this sequence of treatments was not assessed. Evaluation of the efficacy of lactic acid for decontamination of hides was also not performed since all relevant studies submitted evaluated 10 % lactic acid (not the requested maximum of 5 %) or the application method used in the studies was not requested for approval.

The studies described in the selected papers used a wide range of experimental designs and thus differed in relation to products, settings, method of application, lactic acid concentration, use of controls, microorganisms studied, time and temperature of storage, etc. All of these factors impacted on the efficacy both within and between studies. Given this wide range of application conditions, the evaluation

did not attempt to differentiate effects due to different factors, such as lactic acid concentration and temperature of application, within the limits considered, which might influence its efficacy.

Studies on industrial scale and pilot scale which are representative of industrial scale with naturally contaminated products were considered as providing high strength of evidence. Pilot studies with naturally contaminated products and with inoculated pathogenic microorganisms and laboratory studies with naturally contaminated products were considered as providing medium strength of evidence. Laboratory studies with inoculated pathogenic microorganisms were considered as providing low strength of evidence. Based on studies classified by the Panel as of high strength of evidence, lactic acid reduced counts of naturally occurring Enterobacteriaceae on beef carcasses, cuts and trimmings to a variable degree. However, these reductions were usually significantly higher compared to untreated or water treated controls. According to studies classified as of high or medium strength of evidence, lactic acid reduced the prevalence of Salmonella and/or Shiga toxin producing/Verotoxin-producing Escherichia coli (STEC/VTEC) on carcasses, beef cuts and trimmings to varying degrees depending on study design and contamination level. Based on studies classified as of medium strength of evidence, lactic acid was shown to reduce counts of inoculated pathogens (Salmonella and/or STEC/VTEC) on beef carcasses, cuts and trimmings to a variable degree. Usually reductions were higher on carcasses compared to meat cuts and trimmings.

Data to address the issue of the potential emergence of reduced susceptibility to biocides and/or resistance to therapeutic antimicrobials linked to the use of the substance were not provided. It was however concluded that the development of enzymatic resistance to therapeutic antimicrobials as a result of exposure to lactic acid is unlikely. Considering the extensive natural presence of lactic acid in fermented food, the possibility of mutational change resulting in the development of resistance to therapeutic antimicrobials is also unlikely to be a significant issue. There is some evidence that repeated exposure to lactic acid can select for reduced susceptibility to the substance. Under good hygienic practices (GHP), this possibility is not considered a significant issue.

This Scientific Opinion further points out that the concentration of lactic acid just before entering the wastewater treatment system is considered as negligible. For this reason, an environmental risk assessment was considered as not necessary.

It is recommended that, according to HACCP principles, during use, food business operators verify lactic acid concentration, temperature of application and other factors affecting its efficacy as a decontaminating agent. Because of the variability between various studies, it is also recommended that food business operators validate the antimicrobial efficacy under their specific processing conditions.



EUROPEAN COMMISSION

Brussels, XXX
SANCO/.../2011 D017014/02
[...](2011) XXX draft

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

of XXX

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

(Text with EEA relevance)

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

of XXX

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

(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 origin¹¹, 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 foodstuffs¹² 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 foodstuffs¹³ 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.
- (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 trimmings¹⁴.
- (6) In its Opinion, EFSA concludes that the treatments using lactic acid for decontamination of bovine carcasses, 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

¹¹ OJ L 139, 30.4.2004, p. 55.

¹² OJ L 139, 30.4.2004, p. 1.

¹³ OJ L 338, 22.12.2005, p. 1.

¹⁴ EFSA Journal 2011;9(7):2317.

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) 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 applied after the health marking. .
- (9) [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.](#) 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.
- (10) 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 carcasses or half carcasses or quarters at the level of the slaughterhouse in compliance with the conditions set out in the Annexe 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
[\[...\]](#)

ANNEXE

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 following the specifications of Commission Directive 2008/84/EC laying down specific purity criteria¹⁵.
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 after the health marking;
 - (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.

Background history on the use of antimicrobial treatments

- A proposal for the use of four decontaminating substances (chlorine dioxide, acidified sodium chlorite, peroxyacids and trisodium phosphate) to reduce the surface contamination from poultry carcasses was previously rejected at the Standing Committee on the Food Chain and Animal Health (SCoFCAH) on 2 June 2008.
- The EFSA Opinion had been favourable (2005¹⁶), concluding that treatment with the substances under the described conditions of use would be of no safety concern. Further Scientific Committees considering the environmental impact and effect on antimicrobial resistance of the four substances concluded that additional information was required for a proper assessment of the impact and environmental consequences¹⁷.
- The Board was asked to consider the draft proposal and recommended to Ministers that the UK should abstain from the vote¹⁸.
- The proposal was referred to the Agriculture Council (9 December 2008) where it was rejected with a qualified majority. The UK abstained from the vote, all other Member States voted against.
- The US has since requested World Trade Organization (WTO) dispute settlement consultations with the European Union under the WTO Agreement on the Application of Sanitary and Phytosanitary Measures and the General Agreement on Tariffs and Trade 1994 regarding the EU's position on the use of antimicrobial treatments to reduce surface contamination from poultry carcasses on the basis that is judged safe by both US and European food safety authorities.

¹⁶ <http://www.efsa.europa.eu/en/efsajournal/doc/297.pdf>

¹⁷ http://ec.europa.eu/health/archive/ph_risk/committees/04_scenihr/docs/scenihr_o_015.pdf

¹⁸ <http://www.food.gov.uk/multimedia/pdfs/board/boardmins080917.pdf>

ANNEXE 4

Initial views¹⁹ from UK stakeholders on the draft Commission proposal on the use of lactic acid to reduce microbial surface contamination from bovine carcasses, cuts and trimmings

- **British Meat Processing Association (BMPA):** Although members of the BMPA are not in principle opposed to the authorisation of lactic acid on beef carcasses, they are concerned that it could lead to a drop in hygiene standards.
- **The Association of Meat Inspectors (AMI):** The AMI is opposed to the proposal as they claim it may mask poor hygienic practice. If adopted, AMI suggest that lactic acid washing should only take place post health marking and any meat produced in this manner must be clearly labelled as such
- **Unison:** Unison does not support the proposal, but, if adopted, argue that such treatments should be applied only after the post mortem and health marking processes have been completed.
- **Scottish Association of Meat Wholesalers (SAMW):** The SAMW argues that the priority is to exercise control through a policy of only allowing clean cattle to be processed. If approved, use of lactic acid should remain permissive and not mandatory.
- **British Poultry Council (BPC):** The BPC considers the proposal is straightforward with set parameters for lactic acid dilution level and application temperature. They have queried the requirement to demonstrate compliance with microbiological criteria prior to treatment with lactic acid
- **British Retail Consortium (BRC):** BRC members are generally in favour of the proposal provided it is recognised as an additional intervention and not as a substitute for good hygiene and decontamination techniques.
- **Which?:** Which? is concerned that the proposal does not provide for the labelling of products and that consumers would expect meat treated with lactic acid to be labelled.
- **BEUC:** The European consumers' organisation have a general concern that the proposal could undermine the EU approach to food safety controls and they recognise that consumers may not want to eat meat treated in this way and suggest it should be labelled.
- **Defra and the devolved administrations:** Lactic acid, at concentrations of 2% – 5% specified in the proposal, would not be dangerous or toxic. They have queried whether the treatment would be applied before or after the health marking is applied, whether treatment would alter the visual characteristic of the carcass as this may impact on the use of automated carcass classification/grading equipment, whether authorisation of the treatment may lead to a drop in hygiene standards, and raised issues relating to EU-USA trade.

¹⁹ Views received in response to an informal consultation to 85 organisations across the UK