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Evaluation of the safety and efficacy of lactic acid to reduce microbiological surface contamination on carcases from kangaroos, wild pigs, goats and sheep

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Abstract

Studies evaluating the safety and efficacy of lactic acid to reduce microbiological surface contamination from carcases of wild game (i.e. kangaroos and wild pigs) and small stock (i.e. goats and sheep) before chilling at the slaughterhouse were assessed. Wild pig and kangaroo hide-on carcases may have been chilled before they arrive at the slaughterhouse and are treated after removal of the hides. Lactic acid solutions (2–5%) are applied to the carcases at temperatures of up to 55°C by spraying or misting. The treatment lasts 6–7 s per carcass side. The Panel concluded that: [1] the treatment is of no safety concern, provided that the lactic acid complies with the European Union specifications for food additives; [2] based on the available evidence, it was not possible to conclude on the efficacy of spraying or misting lactic acid on kangaroo, wild pig, goats and sheep carcases; [3] treatment of the above-mentioned carcases with lactic acid may induce reduced susceptibility to the same substance, but this can be minimised; there is currently no evidence that prior exposure of food-borne pathogens to lactic acid leads to the occurrence of resistance levels that compromise antimicrobial therapy; and [4] the release of lactic acid is not of concern for the environment, assuming that wastewaters released by the slaughterhouses are treated on-site, if necessary, to counter the potentially low pH caused by lactic acid, in compliance with local rules.

Keywords: lactic acid, wild game and small stock carcases, toxicological safety, efficacy, antimicrobial resistance, environmental impact

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

1.1.1. Background

EU food hygiene legislation is aimed at protecting consumers against potential risks to health and maintaining a high level of consumer protection at all stages of the food chain. This objective must be achieved by applying the appropriate measures, including good hygiene practices and hazard control measures at each step of the food chain.

According to EU scientific advice[1], decontamination practices can be a tool to further reduce the number of pathogenic microorganisms but the use of substances intended to remove microbial surface contamination should only be permitted if a fully integrated control programme is applied throughout the entire food chain. Those substances shall be assessed thoroughly before their use is authorised.

Regulation (EC) No 853/2004[2] prohibits the use of any substance other than potable water (or in certain cases, clean water) to remove surface contamination from products of animal origin. However, Article 3 (2) of this Regulation provides for a derogation from that rule and empowers the Commission to authorise the use of substances other than potable water to remove surface contamination from products of animal origin.

In addition to the safety of the substance, other matters of concern are the potential emergence of reduced susceptibility to biocides, the potential emergence of resistance to therapeutic antimicrobials and the impact of the substance or its by-products on the environment.

Therefore, before taking any risk management decisions on their approval, a risk analysis process should be carried out taking into account the results of a risk assessment based on the available scientific evidence and undertaken in an independent, objective and transparent manner.

EFSA Guidance

On 14 April 2010, the European Food Safety Authority (EFSA) issued a revision of a guidance document[3] 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.

Application for approval

On 20 January 2020, the Commission received an application dossier from the Australian Competent Authorities[4] for the approval of lactic acid for use during processing for the reduction of pathogens on carcases of wild game and small stock.

The dossier is enclosed with this request.

1.1.2. Terms of Reference

In accordance with Article 29 (1) (a) of Regulation (EC) No 178/2002[5], EFSA is requested to evaluate the safety and efficacy of lactic acid intended to be used by food business operators during processing to reduce microbiological surface contamination from carcases of the following wild game: kangaroo, and wild pigs, and of the following small stock: goats and sheep. In particular, the EFSA shall assess:

- The toxicological safety of the substance (ToR 1);
- The efficacy, i.e. does the use of this substance significantly reduce the level of contamination of pathogens on carcases from wild game and small stock aforementioned (ToR 2);
- The potential emergence of reduced susceptibility to biocides and/or resistance to therapeutic antimicrobials linked to the use of the substance (ToR 3);
- The risk related to the release of the processing plant effluents, following the use of the substance, into the environment (ToR 4).

[1] SCVPH: Scientific Committee on Veterinary Measures Relating To Public Health - 1998. Report on the benefits and limitations of antimicrobial treatments for poultry carcasses, 30 October 1998. SCVPH (2003) - Opinion on the evaluation of antimicrobial treatments for poultry carcasses https://ec.euroDa.eu/fs/sc/scv/out63.en.pdf). EFSA Journal 388, 1–19.

[2] Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin. OJ L 139, 30.4.2004, p. 55–205.

[3] EFSA Journal 2010;8(4):1544.

[4] Mr. Greg Read - Exports Division - Department of Agriculture in Canberra – Australia.

[5] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L31, 1.2.2002, p. 1–24.

1.2. Information on existing authorisation and/or evaluations from other authorities

In the European Union (EU), Commission Regulation (EU) No 101/2013[6] authorises the use of lactic acid to reduce microbiological surface contamination on bovine carcases, half or quarter carcases at the level of the slaughterhouse in compliance with the conditions set out in the Annex to this Regulation (up to 5% lactic acid solutions at temperatures of up to 55°C).

USDA FSIS Directive 7120.1[7] authorised the use of pathogen reduction treatments on meat, poultry and egg products. Lactic acid is authorised at concentrations up to 5%.

Health Canada issued Letters of No Objection for antimicrobial processing aids, among which lactic acid is listed.[8]

In 2016, FAO/WHO issued the 'Guidelines for the control of non-typhoidal Salmonella spp. in beef and pork meat'[9] and concluded that organic acid treatments, such as lactic acid washes, can significantly reduce Salmonella prevalence on carcases. The experts considered that the realistic reductions to be possibly achieved would not exceed 1 $\log_{10}$ CFU/cm^2.

In the EU, lactic acid is an authorised food additive (E 270), according to Annex II and Annex III to Regulation (EC) No 1333/2008[10], belonging to group I additives. Its use is permitted in several food categories, mainly at *quantum satis*. As foreseen in Regulation (EC) No 257/2010[11], it is currently re-evaluated.[12]

According to Regulation (EC) No 1333/2008, lactic acid is authorised for use in meat preparations with the following restriction: 'only prepacked preparations of fresh minced meat and meat preparations to which other ingredients than additives or salt have been added'. Moreover, only the L (+)-isomer can be used in food for infants and young children, as specified in category 13.1.

In the EU, lactic acid is also authorised as food flavouring (Commission Regulation (EU) No 1334/2008[13]; FL-no: 08.004).

In 1974, the Joint FAO/WHO Expert Committee on Food Additives (JECFA) issued an opinion on lactic acid and several of its salts, allocating an acceptable daily intake (ADI) of 'not limited' (JECFA, 1974, 1998). In 1991, this ADI was supported by the Scientific Committee of Food (SCF) for lactic acid and its salt when used as food additive (SCF, 1991).

The applicant also informed about the following additional authorisations:

- in Singapore, lactic acid solutions not exceeding 2.5% (w/w) are permitted as an antimicrobial agent on fresh/frozen meat and poultry carcases, cuts and meat, applied as a spray (Documentation provided to EFSA No. 1).
- The Japanese Ministry of Health, Labour and Welfare (MHLW) included lactic acid in the Food Additive list as having no potential to cause damage to human health (Food Sanitation Act 2010[14]).
- In Australia and New Zealand, lactic acid is permitted under the Australia New Zealand Food Standards Code[15] at a level not exceeding that necessary to achieve the technological purpose for which it is applied.

[6] Regulation (EU) No 101/2013 of 4 February 2013 concerning the use of lactic acid to reduce microbiological surface contamination on bovine carcases. OJ L 34, 5.2.2013, p. 1–3.

[7] FSIS Directive 7120.1, Revision 46, Safe and Suitable Ingredients Used in the Production of Meat, Poultry, and Egg Products, 19/3/18 https://www.indiantradeportal.in/uploads/General%20Documents/NU_SPS-TBT/22-03-2018/Production_Of_Meat_Poultry_And_Egg_Products.pdf

[8] Health Canada, 'Antimicrobial Processing Aids for which Health Canada has Issued a Letter of No Objection (LONO) or an interim Letter of No Objection (iLONO)', 17 December 2015.

[9] Codex Alimentarius, 'Guidelines for the control of non-typhoidal Salmonella spp. in beef and pork meat' CAC/GL 87-2016.

[10] Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives OJ L 354, 31.12.2008, p. 16–33. https://data.europa.eu/eli/reg/2008/1333/oj

[11] Regulation (EU) No 257/2010 of 25 March 2010 setting up a programme for the re-evaluation of approved food additives in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives. OJ L 80, 26.3.2010, p. 19–27.

[12] EFSA-Q-2011-00596: re-evaluation of E270, lactic acid.

[13] Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC. OJ L 354, 31.12.2008, p. 34–50. https://data.europa.eu/eli/reg/2008/1334/oj

[14] https://www.jetro.go.jp/ext_images/en/reports/regulations/pdf/foodext2010e.pdf

[15] https://www.foodstandards.gov.au/code/Pages/default.aspx

1.3. Additional information

1.3.1. Introduction

As indicated in the technical dossier, the applicant is seeking approval for Australian meat processors to export to the EU carcases of wild game (wild pigs and kangaroos) and small stock (sheep and goats) treated with lactic acid to reduce microbial contamination. According to the applicant, *'this application is intended to reduce the microbial load, primarily in terms of enteric pathogenic microorganisms (i.e. Campylobacter, verotoxigenic Escherichia coli (e.g. E. coli O157:H7), Salmonella and Listeria monocytogenes). A secondary effect of the application of lactic acid is likely to be a reduction in the load of spoilage microorganisms resulting in an increased product shelf-life'*.

1.3.2. Conditions of use and mode of application

The applicant submitted the following information in relation to the treatment:

- Lactic acid may be applied as a spray or mist onto the surfaces of the sheep, goat, wild pig and kangaroo carcases. It must not be applied to carcases with visible faecal contamination.
- The spraying or misting may be applied at the end of the slaughter line after inspection and final trim prior to entering the chiller. The temperature of the carcass at the time of application will vary depending on the slaughtered species and the temperature in the slaughter house. Typically, surface temperatures of small stock carcases range from 15°C to 30°C prior to entering the chiller. The applicant considers this temperature as not likely to be a factor influencing the efficacy of treatment.
- Game carcases are refrigerated remotely with hides on and arrive at the processing plant in refrigerated vehicles. Application of lactic acid will be after hide removal, immediately before entering the boning room, where the carcass surface temperature is < 7°C.
- Lactic acid will be applied at a concentration of 2–5% and at up to 55°C, using an upper pressure limit of 50 psi.
- The application will be for 6–7 s per carcass side, delivering an amount of lactic acid solution to result in an excess to the point of run-off. For a kangaroo carcass, this is approximately 1 L.
- There will be no removal of residual lactic acid from the carcass surface after treatment.
- The lactic acid solution will not be recycled.

2. Data and methodologies

The present evaluation is based on the data on lactic acid used for the reduction of pathogens on carcases of wild game (kangaroos and wild pigs) and small stock (goats and sheep) provided by the applicant in a dossier submitted in support of the application (see Documentation provided to EFSA No. 1).

Additional information was received from the applicant during the assessment process (see Documentation provided to EFSA No. 2) in response to a request from EFSA sent on 24 February 2021.

To assist the assessment of the safety and efficacy of a decontaminating agent applied to foods of animal origin, in 2010, EFSA issued a guidance document entitled 'Guidance document 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' (EFSA BIOHAZ Panel, 2010). The assessment was conducted in line with the principles described in this guidance document.

2.1. Methodology for ToR1, 3 and 4

ToRs 1, 3 and 4 refer to toxicological safety, potential emergence of resistance to biocides and/or to therapeutic antimicrobials and environmental risk assessment.

The questions as specified in the ToRs 1, 3 and 4 have been addressed by evaluating the information provided by the applicant, supplemented by other information based on the knowledge/ expertise of the Working Group and Panel members.

2.2. Methodology for ToR 2

The question as specified in ToR 2 (efficacy) was addressed by applying a systematic, stepwise approach, as follows:

- Formulation of the question under assessment and definition of the eligibility criteria for selecting experiments in the records provided (e.g. articles published in the scientific literature) and relevant for answering the question(s);
- Ascertainment of the comprehensiveness and relevance of the evidence provided by the applicant;
- Data extraction from the included experiments, using predefined data extraction tables designed to record the required information for the assessment;
- Appraisal of individual experiments included in the assessment, using a predefined critical appraisal tool (CAT) for the reliability evaluation;
- Data synthesis and interpretation of results.

2.2.1. Formulation of the question under assessment and eligibility criteria for study selection

The question under assessment (review question) is whether or not the application of lactic acid can achieve a significant reduction in the surface load of bacterial pathogens on wild pig, kangaroo, sheep and goat carcases after the final wash and before chilling at the slaughterhouse. The pathogens considered include: *Campylobacter* spp., Shiga toxin-producing *E. coli* (STEC) (also called verocytotoxigenic *E. coli* (VTEC)), *Salmonella* spp. and *L. monocytogenes*. The proposed treatments will also reduce spoilage microorganisms, which, according to the applicant, may result in an increased product shelf-life. However, this was not assessed in this opinion.

In the EFSA guidance document (EFSA BIOHAZ Panel, 2010), the use of decontaminating agents in a formulated product, under defined conditions, will be regarded efficacious *'when a reduction of the prevalence and/or numbers of pathogenic target microorganisms set according to determined criteria, is statistically significant*[16] *when compared to a non-treated control group (considering both a control group treated with potable water and a control group not treated at all)'*. In this assessment, the comparison was made with the untreated control if the water treatment control was not included in the experimental design. The EFSA guidance document on the assessment of the biological relevance of data in scientific assessments (EFSA Scientific Committee, 2017) provides a general framework for establishing the biological relevance of observations at various stages of the assessment.

The achieved reduction in contamination should be expected to provide benefits to public health (EFSA BIOHAZ Panel, 2010).

The eligibility criteria for selecting studies for inclusion in the assessment are outlined in Table 1. These have been defined based on the conditions of use and mode of application as provided by the applicant (see Section 1.3.2) and were applied for assessing the relevance of the studies. Enterobacteriaceae, coliforms and/or *E. coli* have been added as indicators. The outcome of interest was a change in numbers ($\log_{10}$ reduction) and/or in the presence of *Campylobacter* spp., STEC/VTEC, *Salmonella* spp., *Listeria* spp., Enterobacteriaceae, coliforms and/or *E. coli* on the treated carcass at any time point after the treatment.

Table 1: Eligibility criteria for study selection related to their characteristics

Criteria related to study characteristics		
Population	In	Wild pig[(a)], kangaroo, sheep and goat carcases before chilling at the slaughterhouse (referred to in the text as pre-chill). Wild pig and kangaroo hide-on carcases may have been chilled before they arrive at the slaughterhouse and are treated after removal of the hides.
Intervention	In	Lactic acid used by spraying or misting at a concentration of 2–5% and at a temperature of up to 55°C for a duration of 6–7 s per carcass side. The concentration and temperature of the lactic acid solution and duration of treatment needed to be reported/ available to assess these aspects.
Comparator	In	Water (or other solution)-treated or untreated controls[(b)]

[16] The extent of reduction is a risk management decision.

Criteria related to study characteristics		
Outcome of interest	In	The change in the presence and/or numbers (log_{10} reduction) of *Campylobacter* spp., STEC/VTEC, *Salmonella* spp., *Listeria* spp., Enterobacteriaceae, coliforms and/or *E. coli* on the treated carcass at any time point after the treatment (e.g. immediately after treatment, during storage or of the retail cuts at the end of shelf-life)
Study design and setting	In	Experimentally controlled studies were included (studies without a control group were excluded). These may have been undertaken in a laboratory, pilot-scale plant or in an industrial (commercial) setting
Criteria related to report characteristics		
Language of the full text	In	English
Time	In	No restriction
Publication type	In	Primary research studies (i.e. studies generating new data)
	Out	Systematic reviews Narrative reviews(b) Expert opinions, editorials and letters to the editors

STEC: Shiga toxin-producing *E. coli*; VTEC: verocytotoxigenic *E. coli*.
(a): Domestic pork is not considered eligible because, compared with wild pigs, the legal definitions, slaughterhouse practices and meat composition differ.
(b): No treatment applied. These carcases or cuts were left as they were without applying organic acids or water or any other solution.

2.2.2. Ascertainment of the comprehensiveness and relevance of the evidence provided by the applicant

Search for studies

In total, 17 potentially relevant records were obtained from the application dossier, of which, one contained an in-house study on kangaroo carcases.

The applicant has provided the following search strings that have been used to retrieve the records covering lactic acid efficacy:

- *'Google search (application of lactic acid to (beef OR pig) carcases)*
- *Google search (temperature and application of lactic acid to (beef OR pig) carcases)*
- *Google search (lactic acid AND sheep carcases)*
- *PubMed ('lactic acid' AND sheep AND decontamination AND carcases)*
- *Google search (body surface area of sheep)*
- *Google search (surface pH of sheep carcases)*
- *Wiley Online Library (search string - Grau F H)*
- *Referenced in* Grau (1983)[17]
- *Referenced in Grau (1980)*[18]'

Study selection process and identification of relevant experiments

Applying the eligibility criteria illustrated in Table 1, the records were screened at full-text level for relevance to the review question in two steps. The reasons for exclusion are reported.

Step I: Identification of records to be excluded: not primary research study, not in English or full text not available.

Step II: Identification of experiments within each record and evaluation of their relevance to the question under assessment based on their objective and the relevant experimental design (e.g. substance, experimental setting, type of contamination, application method, product category and product subcategory). Each experiment was identified by a Ref_ID number and a brief description of its objective. Then, each experiment was screened for relevance to the question under assessment and validated. Possible divergences were solved by discussion within the WG.

[17] Grau FH, 1983. Microbial growth on fat and lean surfaces of vacuum-packaged chilled beef. Journal of Food Science, 48, 326–328. https://doi.org/10.1111/j.1365-2621.1983.tb10735.x
[18] Grau FH, 1980. Inhibition of the anaerobic growth of *Brochothrix thermosphacta* by lactic acid. Applied and Environmental Microbiology, 40, 433–436. https://doi.org/10.1128/aem.40.3.433-436.1980

2.2.3. Data extraction from included experiments

The list of parameters to be extracted from the records included in the assessment was predefined and adapted from EFSA CEF Panel (2018). Excel was used to record the data. The extracted data can be found in Annex A.

The first columns contain the experiment-defining variables, i.e. the experimental setting (laboratory scale, pilot-scale representative of industrial process and industrial scale), the type of contamination (natural or experimental), the substance (lactic acid), the application method (spraying or dipping), the product category (sheep, goat, wild pig or kangaroo carcases pre-chill) and the product subcategory (product as described in the record).

The further columns captured information related to:

- treatment characteristics: the concentration, temperature and pH of the decontamination solution, the duration of treatment and pressure of the application.
- contamination characteristics: the bacterial group (*Campylobacter* spp., STEC/VTEC, *Salmonella* spp., *Listeria* spp., Enterobacteriaceae, coliforms and/or *E. coli*) and subgroup (when provided). In case of experimental contamination, information was captured, when available, on the origin of the strain(s), the pool of strains (if used) and the bacteriological preparation of the strains, including the growth phase of the culture.
- the analytical methods: The analytical method used for monitoring the presence/absence or for enumeration, the method of meat sampling and the limit of quantification for enumeration (to be reported when one of the counts is below the limit of detection).

The last columns captured information related to:

- The treatment and storage characteristics: the treatment of samples, i.e. water, untreated, decontamination solution and both decontamination solution and control (when only $\log_{10}$ reductions were reported), the timing of meat sampling (i.e. before treatment, immediately after treatment, first time point after storage (when immediately after treatment is not available), end of storage) and, if storage is applied, the storage characteristics (i.e. temperature, duration, conditions).
- The outcome extraction: the number of samples tested and/or trials performed, the microbial concentration (central measure, dispersion measure and unit) when enumeration was performed for samples that have been treated with water or the decontamination solution or are left untreated, the number of positive samples and number of samples tested or proportion of positive samples when presence/absence testing was performed.

As in the EFSA CEF Panel (2018), a series of transformations were applied to the data in order to harmonise the measurement unit used in the various experiments. For the comparison and the evaluation of experiments, results were reported as the mean $\log_{10}$ reduction. This is the difference between the means of the $\log_{10}$ concentration of control group and treated group. For the three possible situations for reporting the enumeration outcomes, it is explained in EFSA CEF Panel (2018) how the mean $\log_{10}$ reductions and corresponding 95% confidence intervals (95% CI) of the $\log_{10}$ reductions were calculated.

2.2.4. Appraisal of individual experiments

The strength of each experiment included in the assessment was appraised taking into consideration elements related to relevance and reliability as described in EFSA CEF Panel (2018). Data relevance refers to the appropriateness of the data for the intended purpose of the assessment and the extent to which available data address its objectives (e.g. the right target population, hazard of concern, geographical area, etc.). Reliability refers to precision and accuracy, i.e. the extent to which random error or systematic error (bias), respectively, are minimised.

For assessing the relevance of each experiment, the 'strength of evidence' was defined on a scale high/medium/low based on the experimental setting and type of contamination (see Table 2).

Table 2: Strength of evidence of the contribution of study data to the general body of evidence, based on the experimental setting and type of contamination

Experimental setting	Type of contamination	
	Natural contamination[a]	**Experimental contamination[b]**
Industrial	High	Medium
Pilot-scale[c]	High[d]/medium	Medium
Laboratory	Medium	Low

(a): Includes studies where nothing is deliberately added or inoculated on to the meat surface.
(b): Includes studies where the meat surface is inoculated with laboratory prepared cultures (in suspension or dry form), or with faecal material inoculated or not with laboratory prepared cultures (in suspension or dry form).
(c): Experiments using equipment resembling the industrial applications, but of smaller scale and/or in non-industrial.
(d): If the pilot process is representative of the industrial process, otherwise, evidence makes a 'medium' contribution to the body of evidence.

Each experiment underwent a reliability appraisal through a CAT considering four elements: (a) comparability of control and treated groups, (b) inoculation procedure of the target organism and coverage of the meat surface with the substance, (c) detection and enumeration method of the target organism and (d) statistical analysis and reproducibility (see Appendix A). The rating scale was applied for each element individually and ranged from 1 to 4. For each element listed in the CAT, the experts' judgement was translated into the rating scale shown in Table 3.

Table 3: Proposed rating scale for appraising the reliability of the experiments

Rating	Risk of bias	Precision
4	Definitively low risk of bias	Definitively appropriate
3	Probably low risk of bias	Probably appropriate
2	Probably high risk of bias	Probably not appropriate
1	Definitively high risk of bias	Definitively not appropriate

2.2.5. Data synthesis and interpretation of results in light of identified uncertainties

Each individual experiment included in the assessment was reported in tabular format in the scientific opinion. Each table illustrated the experiment characteristics, population, methods, intervention, outcome(s) and the appraised reliability.

3. Assessment

3.1. Toxicological safety of lactic acid to humans (ToR1)

3.1.1. Identity of the substance

As described by the Panel in the previous EFSA scientific opinion (EFSA CEP Panel, 2018), lactic acid (2-hydroxypropanoic acid, C3H6O3) is a colourless to slightly yellow, nearly odourless, syrupy liquid to solid, soluble in water and water-miscible organic solvents. It is a weak acid (pKa = 3.9 at 25°C) and largely dissociated at biologically relevant pH. There are two optical isomers: L(+) or (S) and D(−) or (R) lactic acid, both of which occur naturally, although the L(+) isomer is the most abundant in all vertebrates, including humans. The structural formula of lactic acid is shown in Figure 1.

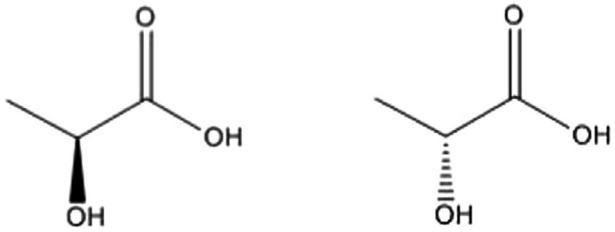

Figure 1: Structural formula of L(+) and D(−) lactic acid

Commercial lactic acid is produced either by fermentation of carbohydrates, such as glucose, sucrose or lactose, or by a chemical synthesis through the formation of lactonitrile from acetaldehyde and hydrogen cyanide, followed by hydrolysis. For food applications, normally L(+) lactic acid made by fermentation is used, but also synthetic lactic acid is accepted, provided the specifications are met (see Table 4).

3.1.2. Specifications

Commercially available food grade lactic acid is used for pathogen reduction treatments, which in the European Union must meet the purity specifications of Commission Regulation (EU) No 231/2012[19] (Table 4).

Table 4: Specifications for solid and aqueous forms of lactic acid (E 270) according to Commission Regulation (EU) No 231/2012

Definition	**Consists of a mixture of lactic acid ($C_3H_6O_3$) and lactic acid lactate ($C_6H_{10}O_5$). It is obtained by the lactic fermentation of sugars or is prepared synthetically. Lactic acid is hygroscopic and when concentrated by boiling, it condenses to form lactic acid**
Einecs	200-018-0
Chemical name	Lactic acid; 2-Hydroxypropionic acid; 1-Hydroxyethane-1-carboxylic acid
Chemical formula	$C_3H_6O_3$
Molecular weight	90.08
Assay	Content not less than 76%
Description	Colourless or yellowish, nearly odourless, syrupy liquid to solid
Identification	
Test for lactate	Passes test
Purity	
Sulfated ash	Not more than 0.1%
Chloride	Not more than 0.2%
Sulfate	Not more than 0.25%
Iron	Not more than 10 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg

Note: This specification refers to an 80% aqueous solution; for weaker aqueous solutions, calculate values corresponding to their lactic acid content.

3.1.3. Analytical method

The concentration of lactic acid in solutions can be verified by titration, e.g. as described by the Joint FAO/WHO Export Committee on Food Additives (JECFA, 2006). The Panel noted that nowadays lactic acid is commonly analysed chromatographically. No method was provided by the applicant for the determination of lactic acid on carcases. The Panel noted that it is difficult to define the relevant surface layer.

[19] Regulation (EU) No 231/2012 of the European Parliament and of the Council of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008. OJ L 83, 22.3.2012, p. 1–280.

3.1.4. Reaction products

As considered by the Panel in the previous EFSA scientific opinion (EFSA CEP Panel, 2018), the decontamination with lactic acid solution temporarily reduces the pH of the meat surface. However, shortly afterwards, the pH returns to near former levels due to the buffering capacity of the meat (Grajales-Lagunes et al., 2012).

The Panel expects no chemical reaction products resulting from the decontamination treatment with lactic acid that would not normally occur in meat.

The application of lactic acid may result in sensory defects in the treated carcases, such as discoloration of the surface, and have an effect on drip and cooking loss due to changes in the water holding capacity of proteins when the pH is near to the isoelectric point (Pipek et al., 2005; Grajales-Lagunes et al., 2012; Mani-Lopez et al., 2012).

Lactic acid is typically purchased as an 80–88% solution and diluted to the desired concentration with potable water. The Panel noted that such water may contain residual chlorine (primarily as hypochlorous acid). This is, however, a very minor amount compared to the lactic acid used and no reaction with lactic acid is expected.

3.1.5. Dietary exposure

Exposure to lactic acid from the intended use was based on consumption of kangaroo, wild pig and small stock (goat and sheep) meat reported in the Comprehensive European Food Consumption Database (see Appendix B). Concentrations of lactic acid in treated meat were retrieved from two sources:

- Concentration data reported by Rose et al. (2004): 12.5 g beef meat pieces treated with 2.5% lactic acid (i.e. 30 g lactic acid/L) took up 0.6 mg lactic acid, equivalent to 48 mg/kg meat. The concentration in meat resulting from the application of 5% lactic acid was extrapolated, based on reported increased uptake between dose intervals, i.e. 0.38 mg/dL from 0.125% to 2% and 0.27 mg/dL from 2% to 2.5%. Therefore, the concentration of the added lactic acid was estimated as **99.2 mg/kg meat**. This estimate was used in the previous EFSA scientific opinion (EFSA CEP Panel, 2018).
- Based on information provided by the applicant (Documentation provided to EFSA No. 2): on a 40-kg sheep, using a 5% lactic acid solution for treatment, 10 g lactic acid can remain on the carcass, which is equivalent to **250 mg lactic acid/kg meat**. The Panel considered that 40 kg is low for sheep, but accepted it as a worst-case scenario, since the heavier the carcass is the lower is the residual amount of lactic acid remaining on the carcass.

The estimated exposure to lactic acid from use as a decontamination agent was compared to that of the endogenous lactic acid in meat.

3.1.5.1. Exposure assessment methodology

The lactic acid concentration data were combined with the average daily consumption of kangaroo, wild pig and small stock (goat and sheep) meat per kilogram body weight for each individual in the Comprehensive Database. Food groups containing these meats were, where necessary, adjusted for the content of these meats (see Appendix B – Table B.2). The resulting exposure was then summed up in order to obtain total chronic exposure at individual level from all food sources. These exposure estimates were averaged over the number of survey days, resulting in an individual average exposure per day for the survey period. The mean and the 95th percentile of the individual exposures were separately calculated for each dietary survey and each population group. The 95th percentile of exposure was only calculated for population groups with a sufficiently large sample size.

3.1.5.2. Exposure to lactic acid

Table 5 shows the exposure to lactic acid from decontamination with 5% lactic acid (the maximum according to the applicant).

Table 5: Exposure to lactic acid from consumption of kangaroo, wild pig and small stock meat resulting from decontamination with 5% lactic acid and using the two estimates of residual lactic acid mentioned above (expressed in mg/kg body weight (bw) per day)

	Infants (12 weeks–111 months)	Toddlers (12–35 months)	Children (3–9 years)	Adolescents (10–17 years)	Adults (18–64 years)	The elderly (≥ 65 years)
99.2 mg residual lactic acid/kg meat (Rose et al., 2004**)**						
• Mean	0–0.013	0–0.033	0–0.062	0–0.009	0–0.027	0–0.023
• 95th percentile	0	0–0.190	0–0.235	0–0.083	0–0.116	0–0.106
250 mg residual lactic acid/kg meat (Documentation provided to EFSA No. 2)						
• Mean	0–0.032	0.001–0.084	0–0.156	0–0.023	0–0.067	0–0.057
• 95th percentile	0	0–0.479	0–0.592	0–0.208	0–0.293	0–0.268

Exposure to lactic acid from the treatment at 99.2 mg lactic acid/kg meat (Rose et al., 2004) ranges for mean from 0 to 0.062 mg/kg bw per day and from 0 to **0.235 mg/kg bw per day** at the 95th percentile across all population groups.

Exposure to lactic acid from the treatment at 250 mg lactic acid/kg meat (Documentation provided to EFSA No. 2) ranges for mean from 0 to 0.156 mg/kg bw per day and from 0 to **0.592 mg/kg bw per day** at the 95th percentile across all population groups.

The Panel brought the above-derived estimates into context with **naturally occurring lactic acid in meat**.

Lactic acid is a natural component of meat, produced by glycolysis of glycogen and glucose in muscle. It is responsible for the pH decrease from around 7.1–7.3 to 5.4–5.7 early post-mortem (Greaser, 1986). The concentration of generated lactic acid is variable, since it depends on factors like resting of the animal before death, content of glycogen in muscles, animal species as well as age, feeding, level of preslaughter stress and activity. Puolanne et al. (2002) calculated that a decline in pH from 7.0 to 5.5 requires the formation of 60–80 mmol lactic acid/kg muscle tissue, which corresponds to a natural content of approximately 0.7% lactic acid in meat.

According to Newbold and Scopes (1967), beef meat at pH~5.7 contains approximately 100 mM lactate. Bendall (1979) observed a similar relationship between pH and lactate concentration in beef, sheep and pig muscle. Livestock production data in Australia identified a dressing percentage for sheep of approximately 45%, with a lean meat yield of around 57%. Therefore, a 40-kg sheep would yield approximately 10 kg lean meat. This would equate to around 90 g of lactate per carcass, i.e. 0.9% lactic acid in meat.

Assuming the lower natural content of 0.7% lactic acid in meat (Puolanne et al., 2002), the intake of endogenous lactic acid from consumption of kangaroo, wild pig and small stock meat is estimated as shown in Table 6.

Table 6: Estimated intake of endogenous lactic acid from consumption of kangaroo, wild pig and small stock meat (expressed in mg/kg bw per day)

	Infants (12 weeks–11 months)	Toddlers (12–35 months)	Children (3–9 years)	Adolescents (10–17 years)	Adults (18–64 years)	The elderly (≥ 65 years)
Natural occurrence of 7 g/kg meat (Puolanne et al., 2002**)**						
• Mean	0–0.9	< 0.1–2.3	0–4.4	< 0.1–0.6	0–1.9	0–1.6
• 95th Percentile	0–0	0–13.4	0–16.6	0–5.8	0–8.2	0–7.5
Natural occurrence of 9 g/kg meat (Bendall, 1979**)**						
• Mean	0–1.1	0–3.0	0–5.6	0–0.8	0–2.4	0–2.1
• 95th Percentile	0–0	0–17.3	0–21.3	0–7.5	0–10.5	0–9.6

Using the data from Puolanne et al. (2002), the intake of lactic acid naturally present in kangaroo, wild pig and small stock meat ranges from 0 to 4.4 mg/kg bw per day at the mean and from 0 to 16.6 mg/kg bw per day at the 95th percentile. Based on the exposure to 0.235 mg/kg bw per day from treatment with lactic acid (Rose et al., 2004), the exposure to endogenous lactic acid at 16.6 mg/kg bw per day is

approximately 70 times higher than the exposure to residual lactic acid from the decontamination treatment.

Using the data from Bendall (1979), the intake of lactic acid naturally present in kangaroo, wild pig and small stock meat ranges from 0 to 5.6 mg/kg bw per day at the mean and from 0 to 21.3 mg/kg bw per day at the 95th percentile. Based on the exposure to 0.592 mg/kg bw per day from treatment with lactic acid (Documentation provided to EFSA No. 2), the exposure to endogenous lactic acid at 21.3 mg/kg bw per day is approximately 36 times higher than the exposure to residual lactic acid coming from the decontamination treatment.

The above exposure estimates do not consider the exposure to lactic acid from other natural dietary sources (e.g. from fermented milk products). Since the exposure to lactic acid from decontamination treatment is considerably low compared to that endogenously present in kangaroo, wild pig and small stock meat, the Panel considered it unnecessary to estimate exposure to lactic acid naturally present in other dietary sources.

3.1.5.3. Uncertainty analysis in dietary exposure assessment

In accordance with the guidance provided in the EFSA Opinion related to uncertainties in dietary exposure assessment (EFSA Scientific Committee, 2007), the following sources of uncertainties have been considered and are summarised in Table 7.

Table 7: Qualitative evaluation of the influence of uncertainties on the dietary exposure estimate

Sources of uncertainties	Direction[(a)]	
	Exposure to lactic acid from use as a decontamination treatment in meat	**Exposure to naturally occurring lactic acid**
Model input data		
Consumption data: different methodologies/representativeness/ underreporting/misreporting/no portion size standard	+/–	+/–
Methodology used to estimate high percentiles (95th) long-term (chronic) exposure based on data from food consumption surveys covering only a few days	+	+
Possible national differences in categorisation and classification of food	+/–	+/–
Assumption that all meat consumed always contains residual lactic acid as a result of treatment with the 5% decontaminating solution	+	NA
Model assumptions and factors		
Use of literature data on use of lactic acid on beef meat (i.e. Rose et al., 2004) or data provided by the applicant (Documentation provided to EFSA No. 2) to calculate the exposure to lactic acid used to decontaminate kangaroo, wild pig and small stock meat	+/–	NA
Use of literature data on use of lactic acid on beef meat (i.e. Rose et al., 2004) or data provided by the applicant (Documentation provided to EFSA No. 2) to extrapolate residual lactic acid following use of a 5% solution.	+/–	NA
Exclusion of natural dietary sources of lactic acid other than from kangaroo, wild pig and small stock meat (e.g. milk fermentation products, fermented fruit- or vegetable-based foods, etc.), in the calculation of the natural dietary intake of lactic acid	NA	–
Adjustment for content of kangaroo, wild pig and small stock meat in food groups containing these types of meats (see Appendix B – Table B.2 'Meat fraction in food groups')	+/–	+/–

(a): + means that the (real) exposure is possibly overestimated, – means that the (real) exposure is possibly underestimated.

In the applied exposure model, the Panel assumed that all kangaroo, wild pig and small stock (goats and sheep) meat consumed always contained residual lactic acid as a result of treatment with the decontamination agent at the highest concentration (5%). This leads to a considerable

overestimation of exposure. In case of Rose et al. (2004), the concentration data applied were extrapolated from beef and the influence of this uncertainty on the exposure assessment cannot be estimated.

Given these observations, the Panel considered that the uncertainties identified would, overall, result in an overestimation of the exposure to lactic acid from its use as a decontamination agent on carcases from wild game and small stock in European countries considered in the EFSA European database.

3.1.6. Toxicological assessment

As in the previous opinion (EFSA CEP Panel, 2018), no toxicological data were provided by the applicant since, according to Commission Regulation (EC) No 1333/2008 on food additives, lactic acid is an authorised food additive that may be used *quantum satis* in a variety of foods, including meat preparations and food intended for infants and young children. The use of lactic acid is also authorised in Europe to reduce microbiological surface contamination on bovine carcases, according to Regulation (EU) No 101/2013[20].

Lactic acid is an endogenous substance. It is an intermediate of carbohydrate and amino acid metabolism produced by almost all human tissues during anaerobic metabolism and in smaller amount by carbohydrate-fermenting bacteria normally present in the gastrointestinal tract. Normal lactate concentrations in human blood are within the approximate range of 0.5–2 mmol/L (Ewaschuk et al., 2005). The L(+) isomer is the major physiological enantiomer present in the human body. D(–) lactate is present in human blood, but usually only at 100 times lower concentration than L(+) lactate (i.e. 5–20 μmol/L) (Talasniemi et al., 2008).

It has been shown that infants in their first 3 months of life have difficulties in metabolising the D(–) isomer and, therefore, they are more susceptible to D(–) lactic acidosis than adults (Petersen, 2005). The capacity to metabolise the D(–) isomer increases with age (Whittakers et al., 1974; Christie and Cranwell, 1976). For this reason, the authorisation of lactic acid as food additive is restricted to the L(+) form in food specially prepared for infants and young children. Considering that meat from kangaroo, wild pig and small stock (goats and sheep) is not consumed by infants in their first 3 months of life, the Panel noted that this restriction is not relevant in the context of the present assessment.

The Panel also noted that D(–) lactic acidosis, defined as plasma D(–) lactate > 3.0 mmol/L in association with metabolic acidosis (blood pH < 7.35) (Uribarri et al., 1998), is one of the many metabolic disorders that can occur in patients with short-bowel syndrome, a rare complication which follows surgical resection of more than half the length of the small intestine. However, only a massive increase in plasma D(–) lactic acid concentration of more than 2.5–3.0 mmol/L (i.e. > 225.2–270.2 mg/L) would lead to the development of D(–) lactic acidosis and symptomatic effects (Ewaschuk et al., 2005). Therefore, even if all the lactic acid used in the decontamination treatment consisted of the D(–) isomer, the maximum expected intake of D(–) lactic acid from the consumption of meat from kangaroos, wild pigs and small stocks (goats and sheep) would only amount to **0.235 mg/kg bw per day** or to **0.592 mg/kg bw/day** (see paragraph 3.1.5.2), not enough to trigger D(–) lactic acidosis in patients with short-bowel syndrome.

Based on the above considerations and noting that exposure to lactic acid from endogenous sources far outweighs exposure from the intended uses (i.e. up to **36- to 70-fold**), the Panel concluded that the use of lactic acid on kangaroo, wild pig and small stock carcases is of no safety concern with respect to toxicity.

3.2. The efficacy of reducing pathogens on carcases from wild game and small stock (ToR2)

3.2.1. Introduction

As mentioned in Section 2.2.1 and in line with the EFSA guidance document (EFSA BIOHAZ Panel, 2010), the use of lactic acid solutions as a decontaminating agent will be regarded as efficacious when a reduction of the prevalence and/or numbers of pathogenic target microorganisms set according to determined criteria, is statistically significant when compared to a control group. The achieved

[20] Commission Regulation (EU) No 101/2013 of 4 February 2013 concerning the use of lactic acid to reduce microbiological surface contamination on bovine carcases.

reduction should be expected to provide benefits to public health, but the required level of this benefit is a risk management decision.

Efficacy has been previously demonstrated to depend on a range of factors, such as the concentration of the decontaminating agent, the microbial pathogen and its load on the surface, contact time, temperature of the decontamination solution (in relation to the carcass temperature), mode of application (i.e. spraying or dipping) and other conditions of use, see, e.g. EFSA BIOHAZ Panel (2011), EFSA BIOHAZ Panel and EFSA CEF Panel (2012) and EFSA CEP Panel (2018).

3.2.2. Study selection and identification of relevant experiments

The search strategy used in the literature searches provided by the applicant was not considered appropriate for the assessment. The search strings that were used by the applicant to retrieve the efficacy records submitted to EFSA are included in Section 2.2.2. No systematic search was conducted in a specific scientific database, such as Web of Science or PubMed for all the target animal species, which may have improved coverage. The date of the searches and search limits were not provided. Moreover, the study selection process used to identify relevant studies has not been provided. Therefore, the comprehensiveness of the evidence provided was not sufficiently demonstrated.

The 17 potentially relevant records derived from the application dossier were screened for eligibility based on the full text (step I and II). In total, 32 experiments were defined. Of these, one record containing a single in-house experiment with kangaroo carcases (Australian Competent Authorities, 2020) fulfilled the criteria for inclusion (see Figure 2 for PRISMA flow chart). A detailed analysis of the number of studies screened, and of the reasons for exclusion is reported in Annex B.

According to this assessment, 16 records did not include any eligible experiments because the studies described were outside the scope for which the applicant is seeking approval. More specifically, 10 records were excluded due to the out-of-scope type/kind of carcass that was used (domestic pork, beef, veal), i.e. Carse and Locker (1974), Grau (1983), Snijders et al. (1985), Dorsa et al. (1997), Castillo et al. (2001), Berman (2003), Rodriguez et al. (2004), King et al. (2005), Pipek et al. (2006), Brustolin et al. (2014). Three other records were excluded because there was no treatment carried out with lactic acid (Newbold and Scopes, 1967; Bendall, 1979; Van de Ven et al., 2014). Another record was excluded because there was no proper control as the water-rinsed lamb breasts were treated with lactic acid, followed by trisodium phosphate (TSP) treatment, or treated exclusively with TSP. Also, the duration of the spraying of the lamb breasts was slightly longer than 6–7 s per carcass side (i.e. 9 s per lamb breast) (Ramirez et al., 2001).

Two records were excluded because the duration of the spraying was longer than 6–7 s per carcass side and the temperature of the lactic acid solution was not specified. More specifically, the duration of the spraying of the sheep carcases was 30 s per thoracal carcass side in the study by Beyaz and Tayar (2010) and the duration of the spraying of the sheep/goat carcases was 2–4 min per forequarter in the study by Dubal et al. (2004). It could be argued that the effect of treatment duration may not be as critical as the other parameters of the treatment, but to evaluate the efficacy of a given time requires a comparative assessment of the efficacy of different treatment durations to establish equivalence under a well-specified treatment set-up (with treatment duration being the only variable factor). Longer treatment durations may result in increased efficacy; however, this could not be evaluated due to lack of studies with comparable treatment configurations (i.e. keeping the other parameters constant such as the concentration, pressure and temperature of the lactic acid solution).

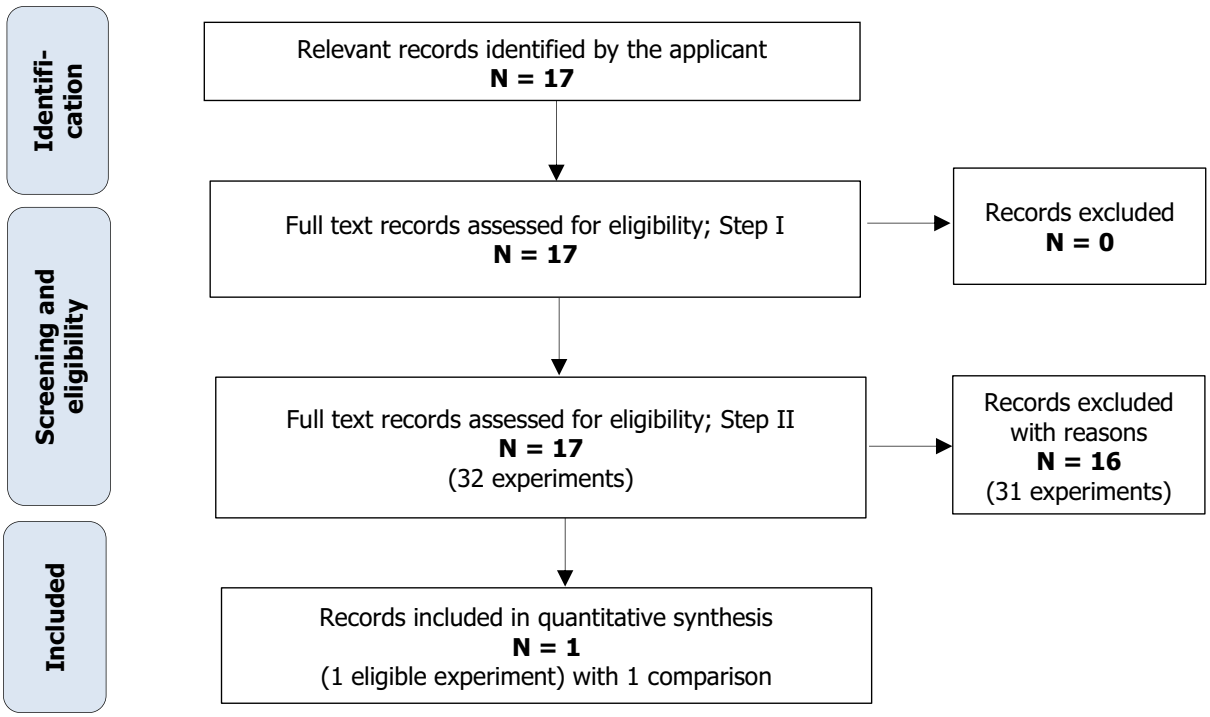

Figure 2: PRISMA flow chart (adapted from Moher et al., 2010)

3.2.3. Description of the eligible experiments

Finally, one experiment from a single record was considered eligible. A summary of the number of experiments by type of carcass treated is given in Table 8. It also considers the method of application and the strength of evidence of the experiment.

An overview of the eligible experiments including a description of the experiment, experimental setting, type of contamination and application method is provided in Table 9. A further description of the eligible experiments considering, amongst others, the treatment characteristics (concentration and temperature of the decontamination solution, duration of treatment and pressure of the application) and the bacterial group, is given in Table 10.

Table 8: Number of eligible experiments by carcass type and application method

Carcass type	Application method	
	Spraying	Misting
Sheep carcases pre-chill	0	0
Goat carcases pre-chill	0	0
Wild pig carcases pre-chill	0	0
Kangaroo carcases pre-chill	One relevant experiment with medium strength of evidence[(a)]	0

(a): Strength of evidence as defined in Table 2.

Table 9: Overview of the single eligible experiment

Experiment no/total no	Ref_ID	Experimental setting	Type of contamination	Strength of evidence[(b)]	Application method	Product category	Product subcategory
1/1	6[(a)]	Industrial	Experimental[(c)]	Medium	Spraying	Kangaroo carcases pre-chill	Kangaroo forequarters

(a): Experiment in the record from the Australian Competent Authorities (2020) with the description: to examine the effect of 3.5% w/v lactic acid spraying (54–55°C; 6 ± 1 s) of kangaroo carcases on the aerobic plate counts (APC) and *E. coli* counts.
(b): High/medium/low strength of evidence as defined in Table 2.
(c): Naturally contaminated faecal material was used for inoculating the meat surface and this is considered as experimental contamination in Table 2.

In the in-house study (Australian Competent Authorities, 2020), carried out at a commercial processing plant, 40 dressed kangaroo carcases/forequarters (pre-chilled, field harvested) were selected for use in the trial and were divided randomly into two lots (20 controls and 20 treated). All forequarters were contaminated on the muscle surface on the shoulder with a diluted suspension of fresh faeces from kangaroos containing approximately 10^6 CFU/mL of *E. coli*. After 20 min to allow for attachment of bacteria in the inoculum to the carcass surface, the first set of carcases was sprayed with hot water (54–55°C) for 7 ± 1 s using a handheld spray system. The second lot of 20 carcases was treated with 3.5% w/v lactic acid solution at 54–55°C for 6 ± 1 s. Carcases were sampled by excising 25 cm^2 of surface tissue from the inoculated area. After collection, the samples were stored at 2–8°C, until analysis commenced the following morning.

Table 10: Description of the single eligible experiment

Experiment no/no of experiments	Ref_ ID	Experi-mental setting	Type of contami-nation	Product category	Product sub-category	Outcome nb	Concen-tration	Temp-erature	Duration	Pressure[(b)]	Bacterial group
1/1	6[(a)]	Industrial	Experimental	Kangaroo carcases pre-chill	Kangaroo for-equarters	OUTC_01	3.5%	54–55°C	6 ± 1 s	NP	*E. coli*

(a): Experiment in the record from the Australian Competent Authorities (2020) with the description: to examine the effect of 3.5% w/v lactic acid spraying (54–55°C; 6 ± 1 s) of kangaroo carcases on the aerobic plate counts (APC) and *E. coli* counts.
(b): NP = not provided.

3.2.4. Synthesis of the results of the eligible experiments

The mean range of lactic acid efficacies (expressed as $\log_{10}$ reductions) for the condition in the eligible experiment (in the record from the Australian Competent Authorities, 2020) is shown in Table 11. Only one comparison is available for *E. coli* from this in-house study immediately after treatment of kangaroo carcases pre-chill with lactic acid. In this experiment, the *E. coli* count prior to any treatment was 4.24 ± 0.27 (standard deviation) $\log_{10}$ CFU/cm^2. After individual treatment with hot water or lactic acid, counts were reduced to 4.15 ± 0.27 and 0.82 ± 0.96 $\log_{10}$ CFU/cm^2, respectively. Hence, the mean reduction estimate, calculated as described in Section 2.2.3, is 3.33 $\log_{10}$ reduction (2.87–3.79 CI_{95}). This greater reduction compared to the water control, immediately after treatment, represents the reductions caused by lactic acid, additionally to the physical removal of contamination caused by water alone.

The appraisal score for this experiment was rated as 4 (definitively low risk of bias) for the question related to comparability of control and treated groups, 3 (probably low risk of bias) for questions related to inoculation procedure of the target organism, 3 (probably low risk of bias) for the question related to detection and enumeration method of the target organism and 3 (probably low risk of bias) for the question related to statistical analysis and reproducibility.

Table 11: Comparisons ($\log_{10}$ reduction estimates) in the eligible study on kangaroo carcases pre-chill treated with lactic acid by spraying

Ref_ID	Bacterial group	Concen-tration	Temp-erature	Duration	Storage	Timing of sampling	Strength of evidence	Control group	Appraisal score	Mean log reduction[(c)]	CI-low	CI-up
6[(a)]	*E. coli*	3.5%	54–55°C	6 ± 1 s	No	Immediately after treatment	Medium	Water	4/3/3/3	3.33	2.87	3.79

(a): Experiment in the record from the Australian Competent Authorities (2020) with the description: to examine the effect of 3.5% w/v lactic acid spraying (54–55°C; 6 ± 1 s) of kangaroo carcases on the aerobic plate counts (APC) and *E. coli* counts.

According to the guidance document (EFSA BIOHAZ Panel, 2010), '*The processing conditions used to evaluate the efficacy must be comparable with those for which the formulated product is intended. The study must include a comparison of the prevalence and/or numbers of the pathogenic microorganisms on the food of animal origin to which the formulated product will be applied and on the untreated control food',* and further on '*The study design should be as close as possible to the real conditions under which the formulated product is intended to be applied'*. It is also spelled out that

'*Justification of the concentration of the product formulation proposed should be experimentally demonstrated, for instance by providing data, showing the effect of different concentrations on the target pathogenic microorganisms reflecting the intended conditions of use*'. Therefore, the evidence on the efficacy of the use of lactic acid that has been generated in previous opinions when applying this substance on beef carcases, cuts and trimmings (EFSA BIOHAZ Panel, 2011) and on pork carcases and pork cuts (EFSA CEP Panel, 2018) could not be used to supplement the information on the use of lactic acid on kangaroo, wild pig, goat and sheep carcases.

Although the relevance of this experiment was considered as of medium strength of evidence and the reliability was scored as definitively/probably low risk of bias (or definitively/probably appropriate), further information is missing that is essential to conclude the assessment.

The eligible experiments do not cover the range of conditions applied for (considering the animal species treated, the pathogens to be removed, the concentration and temperature of the lactic acid solution and the method of application) as:

- Only kangaroo carcases pre-chill were used (no wild pig, goat or sheep carcases);
- Only the indicator organism *E. coli* was tested, while the pathogens applied for are *Campylobacter* spp., STEC, *Salmonella* spp. and *L. monocytogenes*;
- Only 3.5% lactic acid solution was used (range applied for, 2–5%);
- Only lactic acid solution at 54–55°C was used (the application is for all temperatures up to 55°C); and
- Only spraying of the lactic acid solution was used (while misting is also included in the application).

Moreover, for the specific case of kangaroo carcases, as there is only one eligible experiment, the natural variability of the process when applying lactic acid, carcass tissue variability and organism-related factors affecting the efficacy of lactic acid has not been covered. In addition to the above factors, strain variation, as well as variation in inoculum history (e.g. based on different culture preparation protocols, stress adaptation, etc.), initial bacterial load and inoculation method could also influence the efficacy. In addition, samples were only tested immediately after treatment.

3.2.5. Concluding remarks

- Only one experiment was considered eligible for inclusion in the efficacy assessment of lactic acid as a decontaminating agent for wild pig, kangaroo, sheep and goat carcases before chilling at the slaughterhouse.
- That experiment, with a medium strength of evidence, was conducted by spraying 3.5% w/v lactic acid solution at 54–55°C for 6 ± 1 s on kangaroo carcases pre-chill that had been previously inoculated with a faecal suspension containing approximately 10^6 CFU/mL of *E. coli*. The treatment was associated with a reduction of 3.33 $\log_{10}$ (2.87–3.79 CI_{95}) over the water control.
- No data were provided on the efficacy of lactic acid treatment on the pathogens applied for, including *Campylobacter* spp., STEC/VTEC, *Salmonella* spp. and *L. monocytogenes*, or for other treatment conditions using spraying (range of 2–5% applied for and up to 55°C) or misting.
- No data were provided to evaluate the efficacy of lactic acid treatment of wild pig, sheep or goat carcases before or after chilling.
- The methodological approach for collection of the evidence by the applicant was not considered comprehensive and the evidence provided was limited, not covering the whole scope of the application. Therefore, the Panel could not conclude on the efficacy of the lactic acid treatment to decontaminate wild pig, kangaroo, sheep and goat carcases before slaughterhouse chilling.

3.3. The potential emergence of reduced susceptibility to biocides and/or resistance to therapeutic antimicrobials linked to the use of lactic acid (ToR 3)

3.3.1. Information provided by the applicant

In the technical dossier (see Documentation provided to EFSA No. 1), the applicant reported: '*While there is a possibility that exposure to high concentrations of lactic acid or exposure to low*

concentrations for long periods may lead to mutational changes in microorganisms, such changes have not yet been observed and are probably unlikely. Lactic acid is a common food additive or component and microorganisms have been exposed to lactic acid in processed foods (mainly fermented meats and dairy products) at non-lethal concentrations for generations. Exposure to the residual levels in treated carcases is unlikely to add significantly to any mutational changes resulting from exposure to lactic acid'.

3.3.1.1. Promotion of resistance to therapeutic antibiotics

The technical dossier does not provide information on the promotion of resistance to therapeutic antibiotics associated with the use of lactic acid.

3.3.1.2. Development of bacterial resistance to the disinfectant action of lactic acid

The applicant provided the following statement: *'There is the possibility that exposure to high but non-lethal levels of lactic acid during treatment may lead to increased resistance in microorganisms to lactic acid, especially enteric pathogens such as Salmonella and pathogenic E. coli*. *Arvizu-Medrano and Escartin (2005) showed that salmonellae shocked with lactic acid were more tolerant of further acid treatment than un-shocked cells. Acid shock decreased the extension of the lag phase and enhanced the physiological state of the Salmonella when grown at pH 4.5. The duration of the observed acid resistance was not determined. The literature on the likelihood of acid adaption leading to enhanced survival of pathogens in foods is not consistent (Lianou et al., 2012)*. *Lianou et al. (2012) conclude that organic acid treatment is a valuable control intervention that when applied correctly should minimize any observed stress-adaption response. Induced acid resistance is only likely to occur in organisms present in the processing environment. Therefore, induced resistance is only likely to be an issue if cleaning of the process environment is not adequate. Cleaning requirements are detailed in an establishment's approved arrangement which is agreed to by the department. Therefore, the likelihood of acquired resistance in target organisms is considered to be unlikely'*.

3.3.2. Evaluation of the information provided

In a previous EFSA scientific opinion (EFSA CEP Panel, 2018), the potential of lactic acid application for induction of acid adaptation and/or selection of strains that are less susceptible to lactic acid or to therapeutic antibiotics was assessed. It was concluded that although there is some evidence that repeated exposure to lactic acid can select for strains with reduced susceptibility to the same substance, under good hygienic practices (GHP), specifically the effective disinfection of the premises and equipment, it was considered not a significant issue. Moreover, it was concluded that there is no evidence suggesting the emergence of resistance to therapeutic antimicrobials as a result of exposure to lactic acid or horizontally transferable reduced susceptibility to lactic acid.

Since then, Gu et al. (2021) demonstrated a delay in the growth rate but not the maximum biomass of *Salmonella* Derby 14T at pH 4 and identified 35 genes potentially affecting its survival at this pH. Among those genes, the ones encoding CpxRA, a two-component system directly sensing acidification; and CRISPR system Cascade subunits, CasC and CasE, were confirmed to play an essential role in the resistance to acid stress. Such in vitro findings indicate that acid stress induces expression of multiple genes of *S*. Derby, further supporting the potential of mild acid conditions for induction of acid resistance. Based on the overall body of evidence, repeated exposure to lactic acid may lead to selection of lactic acid resistant strains over other more susceptible ones if lactic acid wastes are not treated in an efficient manner under the relevant prerequisite programmes (PRPs), which include GHP. Food businesses are obliged to develop and implement food safety management systems (FSMS) including PRP activities and the principles of hazard analysis and critical control point (HACCP) schemes. PRPs are preventive practices and conditions needed prior to and during the implementation of HACCP, and thus, they are essential for food safety.

As stated in the previous EFSA scientific opinion (EFSA CEP Panel, 2018), adherence to GHP, in particular the application of PRPs (e.g. zoning, cleaning and disinfection, waste management), may minimise the bacterial load on the carcases pre- or post-treatment and prevent the selection of acid resistant strains. Therefore, it is essential to minimise: (i) the pretreatment cross-contamination of the carcases thereby also increasing the likelihood that the lactic acid treatment could be an efficacious intervention, (ii) the probability and duration of exposure of pathogens to sublethal levels of organic acids as a result of unintentional mixing of water and organic acid solutions (carcass run-off) within a meat plant and (iii) the post-treatment cross-contamination of the carcases.

3.3.3. Concluding remarks

- Treatment of wild pig, kangaroo, sheep and goat carcases with lactic acid could potentially increase the ability of bacteria to survive exposure to the substance. This can be minimised through the application of PRPs and ensuring that target application conditions for the decontamination treatments are maintained throughout processing.
- There is currently no evidence that prior exposure of food-borne pathogens to lactic acid leads to the occurrence of resistance levels that compromise antimicrobial therapy.

3.4. Risk related to release of the processing plant effluents linked to the use of lactic acid into the environment (ToR4)

As considered by the Panel in the previous opinion (EFSA CEP Panel, 2018), lactic acid is fully biodegradable. Assuming that the wastewaters released by the slaughterhouses are treated on-site, if necessary to counter the potentially low pH caused by lactic acid, the Panel does not anticipate adverse effects with respect to the release of lactic acid from this application into the environment.

4. Conclusions

4.1. Conclusion regarding ToR 1 on the toxicological safety of lactic acid

- The Panel concluded that treatment of carcases of wild pigs, goats, sheep and kangaroos with lactic acid meeting the specifications of Regulation (EU) No 231/2012 on food additives does not raise a safety concern under the intended conditions of use.

4.2. Conclusions regarding ToR 2 on the efficacy, i.e. does the use of lactic acid significantly reduce the level of contamination of pathogens on carcases from wild game (kangaroos and wild pigs) and small stock (goats and sheep)

- The Panel could not conclude on the efficacy of spraying or misting lactic acid on wild pig, goat and sheep carcases, as none of the submitted documents included an experiment that was found eligible to evaluate the efficacy of lactic acid treatment of these before chilling under the conditions of use.
- Based on the evidence provided, the Panel could not conclude on the efficacy of spraying or misting lactic acid on kangaroo carcases.

4.3. Conclusions regarding ToR 3 on the potential emergence of reduced susceptibility or resistance to therapeutic antimicrobials

- The Panel concluded that treatment of the above-mentioned carcases with lactic acid may induce reduced susceptibility to the same substance, but this can be minimised through the application of PRPs and by ensuring that target application conditions for the decontamination treatments are maintained throughout processing.
- There is currently no evidence that prior exposure of food-borne pathogens to lactic acid leads to the occurrence of resistance levels that compromise antimicrobial therapy.

4.4. Conclusion regarding ToR 4 on the risk related to the release of the processing plant effluents, linked to the use of lactic acid, into the environment

- The Panel concluded that the release of lactic acid is of no concern for the environment, assuming that wastewaters released by the slaughterhouses are treated on-site, if necessary, to counter the potentially low pH caused by lactic acid, in compliance with local rules.

Documentation as provided to EFSA

1) Application for the authorisation of lactic acid intended for use during processing to reduce microbial surface contamination on carcases from wild game and small stock. January 2020.

Submitted by the Australian Department of Agriculture, Water and the Environment (DAWE) (Australia).

2) Additional information, July 2021. Submitted by the Australian Department of Agriculture, Water and the Environment (DAWE) (Australia).

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Abbreviations

APC	aerobic plate counts
BIOHAZ	EFSA Panel on Biological Hazards
CAT	critical appraisal tool
CEP	EFSA Panel on Food Contact Materials, Enzymes and Processing Aids
CFU	colony forming unit
CI	confidence interval
FAO	Food Agriculture Organization of the United Nations
FSMS	food safety management system
GHP	good hygienic practices
HACCP	hazard analysis and critical control point
JECFA	Joint FAO/WHO Expert Committee on Food Additives
PRP	prerequisite programme
STEC	Shiga toxin-producing *E. coli*
ToR	Term of Reference
TSP	trisodium phosphate
VTEC	verocytotoxigenic *E. coli*
WHO	World Health Organization

Appendix A – Critical appraisal tool (CAT) for appraising the reliability of each experiment

No	Question	Rating	Explanation for expert judgement
1	**Comparability of control and treated groups**	4	There is **direct** evidence that the only difference between the treated and control group is the presence or absence of the decontaminating substance and not the method of application or other factors (e.g. inoculated with the target organism using the same procedure, stored at the same temperature and under the same storage conditions, same detection and/or enumeration method used). The control treatment is identical to the treated sample, except for the substance.
		3	There is **direct** evidence of the above (scored 4), except that the control group is left untreated (e.g. no water used). OR There is **indirect** evidence of the above (scored 4)
		2	There is **indirect** evidence that the treated and control group differ in other aspects than being untreated
		1	There is **direct** evidence of the above (scored 2)
2	**Inoculation procedure of the target organism and coverage of the meat surface with the substance**	4	(for experimental contamination) There is **direct** evidence that the inoculum was evenly distributed over the meat surface and that the time between inoculation of the target organism and treatment with the substance was sufficient to allow attachment of the bacteria (e.g. at least 15 min) and the substance was evenly distributed over the meat surface (for natural contamination) There is **direct** evidence the substance was evenly distributed over the meat surface
		3	There is **indirect** evidence of the above (scored 4)
		2	There is **indirect** evidence that the above (scored 4) does not apply
		1	There is **direct** evidence that the above (scored 4) does not apply
3	**Detection and enumeration method of the target organism**	4	There is **direct** evidence that a validated reference method or parts thereof, that enables accurate quantification of the reduction of the bacteria, has been used for the detection and enumeration of the target organism (e.g. FDA method, ISO method)
		3	There is **direct** evidence that an acceptable method other than a validated reference method (e.g. Petrifilm), that enables accurate quantification of the reduction of the bacteria, has been used for the detection and enumeration of the target organism
		2	There is **indirect** evidence of the above (scored 3 or 4)
		1	There is **direct** or **indirect** evidence that the detection and enumeration method contain errors (to be spelled out when scoring)
4	**Statistical analysis and reproducibility**	4	Definitively appropriate: There is **direct** evidence of statistical analysis (e.g. ANOVA, t-test, post hoc test) and independent experimental trials using representative samples (replicates) have been used
		3	Probably appropriate: There is **direct** evidence of statistical analysis but the method and/or the number of independent trials and representative samples (replicates) are not specified
		2	Probably not appropriate: Independent trials (replicates) were used, but there is **direct** evidence that a statistical analysis was not used

No	Question	Rating	Explanation for expert judgement
		1	Definitively not appropriate: A single trial is used (no replicates) and no or insufficient statistical analysis has been performed

Appendix B – Exposure assessment

EFSA Comprehensive European Food Consumption Database

Since 2010, the EFSA Comprehensive European Food Consumption Database (Comprehensive Database) has been populated with national data on food consumption at a detailed level. Competent authorities in the European countries provide EFSA with data on the level of food consumption by the individual consumer from the most recent national dietary survey in their country (cf. Guidance of EFSA on the 'Use of the EFSA Comprehensive European Food Consumption Database in Exposure Assessment' (EFSA, 2011). The version of the Comprehensive database taken into account in this assessment was published July 2021.[21] Data from EU Member States were considered for the estimations.

The food consumption data gathered by EFSA were collected by different methodologies, and thus, direct country-to-country comparisons should be interpreted with caution. Depending on the food category and the level of detail used for exposure calculations, uncertainties could be introduced owing to possible subjects' underreporting and/or misreporting of the consumption amounts. Nevertheless, the EFSA Comprehensive Database includes the currently best available food consumption data across Europe.

Food consumption data from infants, toddlers, children, adolescents, adults and the elderly were used in the exposure assessment. For the present assessment, food consumption data were available from 41 different dietary surveys carried out in 22 European countries (Table B.1). Not all countries provided consumption information for all population groups, and in some cases, the same country provided food consumption data from more than one consumption survey.

Table B.1: Population groups considered for the exposure estimates of lactic acid

Population	Age range	Countries with food consumption surveys covering more than 1 day
Infants	From more than 12 weeks up to and including 11 months of age	Bulgaria, Cyprus, Denmark, Estonia, Finland, France, Germany, Italy, Latvia, Portugal, Slovenia
Toddlers[(a)]	From 12 months up to and including 35 months of age	Belgium, Bulgaria, Cyprus, Denmark, Estonia, Finland, France, Germany, Hungary, Italy, Latvia, Netherlands, Portugal, Slovenia, Spain
Children [(b)]	From 36 months up to and including 9 years of age	Austria, Belgium, Bulgaria, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Italy, Latvia, Netherlands, Portugal, Spain, Sweden
Adolescents	From 10 years up to and including 17 years of age	Austria, Belgium, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Italy, Latvia, Netherlands, Portugal, Slovenia, Spain, Sweden
Adults	From 18 years up to and including 64 years of age	Austria, Belgium, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Netherlands, Portugal, Slovenia, Spain, Sweden
The elderly [(b)]	From 65 years of age and older	Austria, Belgium, Cyprus, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Netherlands, Portugal, Romania, Slovenia, Spain, Sweden

(a): The term 'toddlers' in the Comprehensive Database (EFSA, 2011) corresponds to 'young children' in Regulations (EC) No 1333/2008 and (EU) No 609/2013.
(b): The terms 'children' and 'the elderly' correspond, respectively, to 'other children' and the merge of 'elderly' and 'very elderly' in Comprehensive Database (EFSA, 2011).

Since 2018, all consumption records in the Comprehensive Database are codified according to the FoodEx2 classification system (EFSA, 2015).

[21] https://www.efsa.europa.eu/en/data-report/food-consumption-data

Food categories considered for the exposure assessment to lactic acid

The applicant is seeking approval for the application of lactic acid to wild game (wild pigs and kangaroos) and small stock (sheep and goats) carcases. Foods corresponding to these meat were selected from the nomenclature of the EFSA Comprehensive Database (FoodEx2 classification system), at the most detailed level possible (up to FoodEx2 Level 7) (EFSA, 2015). Table B.2 shows the foods with the percentage of meat within the product and the occurrence levels used.

Table B.2: Foods selected for the exposure estimates to lactic acid

BASICFOODEX2	Basic Foodex2 code	Meat fraction in food group	Lactic acid as decontamination agent		Lactic acid naturally present in meat	
			Level 1 (Rose et al., 2004)	Level 2 (Documentation provided to EFSA No. 2)	Level 1 (Poulanne et al., 2002)	Level 2 (Bendall et al., 1979)
Meat balls	10489776	0.5	99.2	250	7,000	9,000
Goulash	10489757	0.5	99.2	250	7,000	9,000
Moussaka	10489774	0.5	99.2	250	7,000	9,000
Sheep other slaughtering products	10487857	1	99.2	250	7,000	9,000
Sheep kidney	10487766	1	99.2	250	7,000	9,000
Wild boar liver	10487740	1	99.2	250	7,000	9,000
Sheep fat tissue	10487691	1	99.2	250	7,000	9,000
Sheep liver	10487731	1	99.2	250	7,000	9,000
Goat liver	10487732	1	99.2	250	7,000	9,000
Sheep edible offal, non-muscle, other than liver and kidney	10487800	1	99.2	250	7,000	9,000
Sheep fresh meat	10487601	1	99.2	250	7,000	9,000
Fresh spiced sausages in casing	10487954	0.5	99.2	250	7,000	9,000
Mixed beef and mutton/lamb fresh meat	10487672	1	99.2	250	7,000	9,000
Sheep (adult) fresh meat	10487602	1	99.2	250	7,000	9,000
Lamb fresh meat	10487603	1	99.2	250	7,000	9,000
Goat fresh meat	10487604	1	99.2	250	7,000	9,000
Sheep, minced meat	10490196	1	99.2	250	7,000	9,000
Meat stew	10489758	0.5	99.2	250	7,000	9,000

BASICFOODEX2	Basic Foodex2 code	Meat fraction in food group	Lactic acid as decontamination agent		Lactic acid naturally present in meat	
			Level 1 (Rose et al., 2004)	Level 2 (Documentation provided to EFSA No. 2)	Level 1 (Poulanne et al., 2002)	Level 2 (Bendall et al., 1979)
Mammals other slaughtering products	10501237	1	99.2	250	7,000	9,000
Pastrami, lamb	10487946	1	99.2	250	7,000	9,000
Kangaroo fresh meat	10487610	1	99.2	250	7,000	9,000
Wild boar fresh meat	10487633	1	99.2	250	7,000	9,000
Wild boar, minced meat	10490264	1	99.2	250	7,000	9,000
Sheep tallow	10489099	1	99.2	250	7,000	9,000

Annex A – Data extracted from the eligible experiments

Annex A can be found in the online version of this output ('Supporting information' section): https://doi.org/10.2903/j.efsa.2022.7265

Annex B – List of records excluded during the screening for eligibility

Annex B can be found in the online version of this output ('Supporting information' section): https://doi.org/10.2903/j.efsa.2022.7265