

ADOPTED: 5 July 2017

doi: 10.2903/j.efsa.2017.4938

## Safety of lactic acid and calcium lactate when used as technological additives for all animal species

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### Abstract

The additives under assessment are lactic acid and calcium lactate. In 2015, the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) delivered an Opinion on the safety and efficacy of lactic acid and calcium lactate. The FEEDAP Panel could not conclude on the safety of lactic acid in pre-ruminants and poultry. Following this opinion, the European Commission gave the possibility to the applicant to submit complementary information in order to complete the assessment on the safety for all animal species. Based on the studies submitted in chickens for fattening and laying hens, no safe concentration of lactic acid and calcium lactate in complete feed for these species could be identified. Owing to the absence of data on tolerated dietary levels of D-lactic acid, no conclusion on the safety of lactic acid in milk replacer for pre-ruminants is possible. Since a safe concentration of lactic acid (and calcium lactate) was established only for pigs and cattle, and not for a third major animal species, no extrapolation to any other species is possible.

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**Keywords:** lactic acid, calcium lactate, technological, preservative, all animal species

**Requestor:** European Commission

**Question number:** EFSA-Q-2016-00645

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**Acknowledgements:** The Panel wishes to thank the members of the Working Group on Technological additives, including Anne-Katrine Lundebye, Carlo Nebbia and Derek Renshaw, for the preparatory work on this scientific opinion.

**Suggested citation:** EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Rychen G, Aquilina G, Azimonti G, Bampidis V, Bastos ML, Bories G, Chesson A, Coconcelli PS, Flachowsky G, Kolar B, Kouba M, López-Alonso M, López Puente S, Mantovani A, Mayo B, Ramos F, Saarela M, Villa RE, Wallace RJ, Wester P, Lundebye A-K, Nebbia C, Renshaw D, Innocenti ML and Gropp J, 2017. Scientific Opinion on the safety of lactic acid and calcium lactate when used as technological additives for all animal species. *EFSA Journal* 2017; 15(7):4938, 10 pp. <https://doi.org/10.2903/j.efsa.2017.4938>

**ISSN:** 1831-4732

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The EFSA Journal is a publication of the European Food Safety Authority, an agency of the European Union.



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## 1. Introduction

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

Regulation (EC) No 1831/2003<sup>1</sup> establishes the rules governing the Community authorisation of additives for use in animal nutrition and in particular, Article 9 thereof defines the terms of such authorisation by the Commission.

The applicant, ACIAC EEIG (Acids Authorisation Consortium European Economic Interest Grouping),<sup>2</sup> is seeking a Community authorisation of lactic acid and calcium lactate for all animal species. (Table 1)

**Table 1:** Description of the substances

<b>Category of additive</b>	Technological additive
<b>Functional group of additive</b>	Preservatives
<b>Description</b>	Lactic acid and calcium lactate
<b>Target animal category</b>	All animal species
<b>Applicant</b>	Acids Authorisation Consortium European Economic Interest Grouping
<b>Type of request</b>	New opinion

On 9 July 2015, the Panel on Additives and Products or Substances used in Animal Feed of the European Food Safety Authority ('Authority'), in its opinion on the safety and efficacy of the product, could not conclude on the safety of lactic acid in pre-ruminants and poultry.

The Commission gave the possibility to the applicant to submit complementary information in order to complete the safety assessment and allow a revision of the Authority's opinion.

The Commission has now received new data on the safety of lactic acid and calcium lactate.

In view of the above, the Commission asks the Authority to deliver a new opinion on the safety of lactic acid and calcium lactate for all animal species based on the additional data submitted by the applicant.

### 1.2. Additional information

Lactic acid and calcium lactate are presently listed in the European Union (EU) Register of Feed Additives as technological additives (functional group: preservatives) for use with feed for all animal species and categories without restrictions, and are subject to re-evaluation.

Lactic acid has been recently authorised for use as a feed flavouring up to 5 mg/kg (Regulation (EU) 2017/56).

Lactic acid (E 270) and calcium lactate (E 327) are permitted food additives used in a variety of foods (e.g. nectars, jam, jellies, marmalades, mozzarella and whey cheese, fats of animal or vegetable origin for cooking and/or frying, canned and bottled fruits and vegetables, fresh pasta, beer) according to Regulation (EC) No 1333/2008 on food additives. Specifications for purity are laid down in Directive 2008/84/EC.

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) issued an opinion on lactic acid and calcium lactate (JECFA, 1974) allocating an acceptable daily intake (ADI) of 'not limited'. In 1991, this ADI was supported by the Scientific Committee of Food (EC, 1991) and in 2006 iterated in the evaluation of lactate and sodium lactate for poultry carcass treatment (EFSA, 2008). The European Food Safety Authority (EFSA) has issued several opinions on the use of lactic acid and calcium lactate for carcass decontamination (EFSA, 2006, 2008, 2011).

The EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) adopted, in 2015, an opinion on the safety and efficacy of lactic acid and calcium lactate as technological additives for all animal species (EFSA FEEDAP Panel, 2015). In that opinion, the FEEDAP Panel could not conclude on the safety of the additive in pre-ruminants and poultry.

The applicant has submitted additional information related to the safety of lactic acid and calcium lactate and this new information is the subject of this opinion.

<sup>1</sup> Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition. OJ L 268, 18.10.2003, p. 29.

<sup>2</sup> On 13/3/2013, EFSA was informed by the applicant that ACIAC EEIG was liquidated on 19/12/2012 and their rights as applicant were transferred to FEFANA asbl (EU Association of Specialty Feed Ingredients and their Mixtures).

## 2. Data and methodologies

### 2.1. Data

The present assessment is based on data submitted by the applicant in the form of additional information<sup>3</sup> to a previous application on the same product.<sup>4</sup>

### 2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety of lactic acid and calcium lactate is in line with the principles laid down in Regulation (EC) No 429/2008<sup>5</sup> and the relevant guidance documents: Guidance on technological additives (EFSA FEEDAP Panel, 2012) and Technical guidance: Tolerance and efficacy studies in target animals (EFSA FEEDAP Panel, 2011).

## 3. Assessment

The additives under assessment are lactic acid (E 270) and its calcium salt (calcium lactate (E 327)). Lactic acid is produced by four strains of *Bacillus* spp. (*Bacillus coagulans* (LMG S-26145) and (DSM 23965), *Bacillus smithii* (LMG S-27890), *Bacillus subtilis* (LMG S-27889)). Lactic acid is proposed to contain a minimum of 90% of the enantiomer  $\iota$ (+)-lactic acid and a maximum of 10% of the enantiomer  $\delta$ (-)-lactic acid. The lactic acid additive is provided as an aqueous solution specified to contain a minimum of 72% (w/w) lactic acid. The additive calcium lactate is produced by neutralising lactic acid with calcium hydroxide, and it is specified to contain  $\geq 98\%$  (as dry matter (DM), w/w) calcium lactate. Lactic acid and calcium lactate are intended to be used as preservatives in feedingstuffs for all animal species.

In the original application, the proposed maximum use levels were: 50,000 mg lactic acid/kg complete feed, 30,000 mg calcium lactate/kg complete feed and 30,000 mg lactic acid/L in water for drinking, in all animal species. In its previous opinion (EFSA FEEDAP Panel, 2015), the Panel concluded that lactic acid (and its calcium salt) is safe for pigs and functional ruminants at concentrations up to 50,000 mg/kg complete feed and 30,000 mg calcium lactate/kg complete feed (and 15,000 mg lactic acid/L water for pigs). The Panel also concluded that: 'In the absence of data, no conclusions on the safety of lactic acid in pre-ruminants and laying hens can be drawn. Considering the limited number of published studies and the inconsistency of the results reported, it is not possible to conclude on the safety of lactic acid in chickens for fattening'. Therefore, the Panel was not in the position to conclude on the safety of the additive for all animal species. The applicant is now proposing new maximum contents in feedingstuffs for poultry, pre-ruminants and cats and dogs and submitting new information to support the safety for target animals.

### 3.1. Conditions of use

Lactic acid and calcium lactate (anhydrous and hydrate) are proposed for use as preservatives in feedingstuffs, and in water for drinking in the case of the lactic acid, for all animal species and categories. In the original application, the proposed maximum content was 50,000 mg lactic acid/kg feed, 30,000 mg calcium lactate kg/complete feed and 30,000 mg lactic acid/L water. The applicant is proposing new conditions of use with regards to the original application. The newly proposed maximum contents are:

- i) Poultry for fattening and poultry reared for laying or breeding: 20,000 mg lactic acid/kg complete feed, 24,000 mg calcium lactate/kg feed or 30,000 mg calcium lactate hydrate/kg feed and 8,000 mg lactic acid/L water.
- ii) Laying poultry: 10,000 mg lactic acid/kg complete feed, 24,000 mg calcium lactate/kg feed or 30,000 mg calcium lactate hydrate/kg feed and 4,000 mg lactic acid/L water.
- iii) Calves and other young ruminants: 8,000 mg lactic acid/kg milk replacer.
- iv) Dogs and cats: 20,000 mg lactic acid/kg complete feed, 24,000 mg calcium lactate/kg feed or 30,000 mg calcium lactate hydrate/kg feed.

<sup>3</sup> FEED dossier reference: FAD-2016-0053.

<sup>4</sup> FEED dossier reference: FAD-2010-0133.

<sup>5</sup> Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives. OJ L 133, 22.5.2008, p. 1.

## 3.2. Safety for the target species

In the scientific opinion on the safety and efficacy of lactic acid (LA) and calcium lactate (EFSA FEEDAP Panel, 2015), the FEEDAP Panel concluded that 'The maximum recommended levels of 50,000 mg lactic acid/kg complete feed and 30,000 mg calcium lactate/kg complete feed are considered safe for functional ruminants and pigs. The maximum safe concentration of lactic acid for pigs in water for drinking can be derived from the maximum safe level in feed (15,000 mg/L water). No conclusions on the safety of lactic acid in pre-ruminants and poultry can be drawn. These conclusions cannot be extrapolated to other animal species/categories'.

The applicant provided additional published and unpublished studies in chickens for fattening (a total of 10 studies) and laying hens (a total of six studies) and a review on the role of organic acids in poultry nutrition. None of the studies available complies with the requirements for a tolerance study laid down in the EFSA Technical Guidance: Tolerance and efficacy studies in target animals.

No new studies have been provided for pre-ruminants, cats and dogs.

### 3.2.1. Safety for poultry

#### 3.2.1.1. Safety for chickens for fattening<sup>6</sup>

The applicant submitted reports of 10 studies with chickens for fattening. Five of these studies were not considered further because lactic acid was added to the final feed together with other acids in four cases, and because of the study duration (8 days) in the last one. The other five were considered for the assessment. The Panel notes that three of them (Khalid et al., 2002; Missotten et al., 2013; and Adil et al., 2010, 2011) were already assessed in the previous opinion (EFSA FEEDAP Panel, 2015).

The effects of lactic acid on performance of male chickens for fattening fed diets supplemented with 0 or 20,000 mg LA/kg for 42 days were investigated. The performance parameters give an indication that lactic acid is tolerated at 20,000 mg LA/kg feed.<sup>7</sup>

Khalid et al. (2002) studied the effect of diets supplemented with 0, 10,000, 20,000 or 30,000 mg LA/kg on the performance of chickens for fattening. The basal diet consisted mainly of rice (and maize in the finisher) and soybean meal and was fed as a starter (days 1–28, 20% CP, 11.7 MJ ME/kg) or as a finisher ration (days 29–42, 18.5% CP, 12.1 MJ ME/kg). Group size was four replicates with 10 chickens each; the experiment lasted 42 days. Parameters measured were body weight (gain), feed intake, feed to gain ratio and mortality. Data were subjected to an ANOVA with subsequent least significant difference (LSD) test for group differences. Significance was set at  $p < 0.05$ . No mortality was observed. Body weight gain in the starter period was significantly reduced compared to the control by 14%, 11% and 5% in the groups with 10,000, 20,000 and 30,000 mg LA/kg, respectively, whereas feed intake was not affected. In the finisher period, body weight gain of the lactic acid supplemented groups was higher (as a mean by 25%, not dose dependent) and, although feed intake increased by lactic acid supplementation, feed to gain ratio was significantly reduced in these groups (as a mean: 1.78 vs 2.04 in the control group). Cumulative data were not given; however, final body weight and total feed intake could be derived from the data and feed to gain ratios estimated. The lactic acid groups consumed about 100 g feed/bird more than the control, cumulative body weight gain was 1.96, 1.94 and 2.06 kg in the groups 10,000, 20,000 and 30,000 mg LA/kg compared to 1.87 in the control group. The feed to gain ratios were estimated to be 1.77, 1.75 and 1.72 compared with 1.79 for the above groups, respectively. The small number of replicates with a low number of unsexed birds per group does not allow definite conclusions on zootechnical performance. It appears that a strong depression of weight gain in the first 4 weeks of life was fully compensated in the subsequent 2 weeks. A dose relation on the effect of lactic acid on average daily gain could not be seen in the two periods, starter and finisher phase.

Abdel-Fattah et al. (2008) studied the effect of adding 0, 15,000 and 30,000 mg LA/kg complete diet for chickens for fattening for 42 days. The maize, soybean and maize gluten type diet was fed for the first 3 weeks as starter (22.1% CP, 12.5 MJ ME/kg) followed by a finisher diet (18.2% CP, 13.1 MJ ME/kg) until study completion. Group size was three replicates with nine chickens (mixed sex) each. Experimental parameters were indicators of thyroid function (serum T3 and T4), some blood constituents (total protein, albumin, globulin, cholesterol, total lipids, calcium, phosphorus, uric acid, aspartate transaminase (AST) and alanine transaminase (ALT)) organ/tissues weight<sup>8</sup> and performance of chicken for fattening. At the end of the study, 10 birds per treatment were taken for blood sample

<sup>6</sup> This section has been amended following the confidentiality claims made by the applicant.

<sup>7</sup> Additional information August 2016.

<sup>8</sup> Liver, heart, pancreas, small intestine, spleen, bursa, thymus and abdominal fat.

collection and subsequently killed. Data were subjected to an ANOVA, group differences were examined by Duncan's multiple range test. Significance was set at  $p < 0.05$ . No differences were seen in the 3-week body weight between the groups with 0, 15,000 and 30,000 mg LA/kg, the lactic acid groups consumed less feed and had consequently a better feed to gain ratio. At the end of the study, body weight of the lactic acid groups (1.69 and 1.75 kg) was significantly higher than that of the control group (1.59 kg). Feed intake and feed to gain ratio were improved correspondingly. Both levels of lactic acid reduced significantly serum concentrations of cholesterol and total lipids and increased those of calcium, phosphorus (high level lactic acid only) and globulin (high level lactic acid only). In the absence of data on markers of the endocrine system regulating Ca and P serum concentration, the elevated Ca and P levels are considered as adverse. Serum T4 was not affected by lactic acid; however, both lactic acid levels resulted in a significant increase of serum T3. Relative weight of liver, spleen and heart was not affected by either levels of lactic acid, the highest dose of lactic acid resulted in a significant increase of the relative weight of pancreas, bursa and thymus (both lactic acid levels). The low number of replicates and birds per replicate and the unknown (not reported) proportion of sex in the replicates introduce a high level of uncertainty in conclusions on zootechnical performance. No adverse effects on the zootechnical parameters were seen, even in the first 3 weeks of age.

In the study described in Adil et al. (2010, 2011), diets containing 0, 20,000 and 30,000 mg LA/kg were fed to 1-week old Cobb chicken for fattening for 35 days (from day 7 to day 42 of age). Group size was three replicates with 15 chickens (mixed sex) each. The diets consisted mainly of maize, soybean meal and fishmeal and were fed as starter (until day 21, 22.5% CP, 12.0 MJ ME/kg) and as finisher (from day 22, 20.2% CP, 12.3 MJ ME/kg). Parameters measured were body weight (gain), feed intake and feed to gain ratio. In addition, at the end of the study, six birds per treatment were killed and blood samples collected for clinical blood chemistry (glucose, cholesterol, calcium, phosphorus, AST and ALT). Carcass composition (including also liver weight) and gut histology (villus height, crypt depth and muscularis thickness of duodenum, jejunum and ileum) were analysed. Data were statistically examined by ANOVA, group differences by Duncan's multiple range test. Significance was set at  $p < 0.05$ . Both dietary lactic acid concentrations significantly improved final body weight and feed to gain ratio compared to the control (1,602 kg and 1,673 kg vs 1,525 kg). Villus height was significantly increased for 20,000 mg LA/kg in the jejunum, for 30,000 mg/kg in both, the jejunum and the duodenum. No other changes in gut morphology were found. Significant (dose dependent) increases in serum calcium were seen for both lactic acid concentrations and in serum phosphorus for 30,000 mg LA/kg. In the absence of data on markers of the endocrine system regulating Ca and P serum concentration, the elevated Ca and P levels are treated as adverse. No other significant changes were found. The small number of replicates does not allow definite conclusions on the effects of lactic acid on chicken performance, particularly when considering the low 42-day body weight of the control group (1,525 g).

Missotten et al. (2013) studied a different way to include lactic acid in the diets, comparing a mash feed with the same feed after 48-h fermentation (at 26°C) with *Lactobacillus plantarum*. The study lasted 39 days. Group size was seven replicates per treatment with 20 birds each (Ross 308, both sexes). The diet consisted mainly of wheat, was phase fed (starter (days 1–13, 20.8 CP, 6.2% EE; grower (days 14–26, 20.0% CP, 6.6% EE; and finisher (days 27–39, 18.9% CP, 7.7% EE), with decreasing amounts of soybean and maize from starter to finisher. Starter, grower and finisher fermented diets had a pH of 3.9, 4.1 and 4.4, a dry matter content of 40.9%, 40.2% and 39.5% and contained about 64,000, 42,000 and 31,000 mg LA/kg DM, respectively. Experimental parameters were body weight, feed intake and feed to gain ratio (mortality corrected). In addition, at the end of the study, 14 birds per treatment were killed and samples collected for measurement of digesta pH and analysis of gut morphology and carcass quality. Statistical examination was done by one-way ANOVA. Mortality was significantly lower in the group with the fermented feed (3.6%) as in the control group (9.3%). The fermented starter diet significantly decreased feed intake and body weight gain by 45% and 40%, respectively, compared to the control. The corresponding figures for the grower period were 16% and 23% lower, respectively. In the finisher phase, the fermented diet had no influence on body weight gain and lead only to a small but significant reduction of feed intake (5%). For the entire period, body weight of the control group was 2,404 g, that of the group with fermented feed 2,142 g (89% of the control), feed intake was 92 and 79 g/day (85% of the control) and feed to gain ratio, corrected to the same body weight, was 1.47 and 1.51 (103% of the control), respectively. Villus height of small intestine tissue was greater in birds fed the fermented diet(s). Although the two diets differed in more aspects than the lactic acid content alone, it appears that concentrations higher than

42,000 mg LA/kg feed DM (approximately 37,000 mg LA/kg standardised complete feed) are not tolerated by chicken for fattening.

### 3.2.1.2. Safety for laying hens

The applicant submitted six studies from the published literature of which only one could be considered. Of the other five studies, one did not use lactic acid, and in the other four lactic acid was added to the final feed together with other acids.

In the study of Sullivan and Kingan (1962), 16 experimental diets were included, investigating four levels of calcium (1.8%, 2.8%, 3.8% and 4.8%), two levels of ascorbic acid (0 and 55 mg/kg), and two levels of calcium lactate (0% or 1% (equivalent to approximately 8,000 mg LA/kg)). All diets were maintained iso-caloric and iso-nitrogenous. Each treatment consisted of 10 white leghorn hens individually housed. The experiment lasted 46 weeks. The only parameters reported in the study were egg production, shell thickness and specific gravity. The data were analysed by ANOVA followed by Duncan's multiple range test for group differences. Significance was set at  $p < 0.05$ . No negative effects of calcium lactate on egg production and feed efficiency were observed. An increased egg production was observed when the diet contained 2.8% of calcium. The authors reported some tendency of calcium lactate to decrease egg specific gravity and shell thickness.

### 3.2.1.3. Conclusions on the safety for poultry

From the five studies considered with chickens for fattening, it would appear that dietary concentrations of lactic acid higher than 40,000 mg/kg are not tolerated. Although no adverse effect on performance parameters were observed at 30,000 mg LA/kg, the concomitant increase in serum calcium and phosphorus beginning at 15,000 LA/kg is considered as an adverse effect. Therefore, no safe concentration of lactic acid in complete feed for chickens for fattening could be identified.

From the single study available for laying hens, it cannot be excluded that lactic acid at about 8,000 mg/kg feed (equivalent concentration to 10,000 mg calcium lactate/kg feed) negatively affects egg shell quality. Consequently, a safe dose for laying hens cannot be identified.

## 3.2.2. Safety for pre-ruminants

In the previous opinion, the FEEDAP Panel concluded that 'the maximum recommended level of 50,000 mg lactic acid/kg complete feed is considered safe for functional ruminants. In the absence of data, no conclusion on the safety of lactic acid in pre-ruminants can be drawn'.

No new information has been provided to support the safety of lactic acid for pre-ruminants. Instead, the applicant proposes a reduction of the maximum content of lactic acid in milk replacer from 50,000 to 8,000 mg/kg. The applicant made this proposal in order to reduce the exposure of pre-ruminants to D-lactic acid. Considering that the proposed specification for lactic acid is > 90% L-lactic acid and < 10% D-lactic acid, the maximum exposure by calves to D-lactic acid would be 800 mg/kg milk replacer under practical conditions of use.

In the previous opinion, it was recognised that 'When the rate of D-lactate production exceeds the body's capacity for its metabolism and excretion, D-lactate accumulates in the blood causing metabolic acidosis. D-lactate acidosis is well known and described in veterinary medicine as a consequence of grain overfeeding in adult ruminants and in neonatal animals with diarrhoea' (Ewaschuk et al., 2005). The same authors mention that malfunctioning of the oesophageal groove leads to the accumulation of milk in the rumen resulting in fermentation of lactose and D-lactic acidosis. More recent publications indicate that certain clinical signs of neonatal diarrhoea are influenced more by D-lactate concentration than the degree of acidosis (reviewed by Lorenz and Gentile, 2014). Serum concentrations of D-lactic acid in healthy calves and in calves with diarrhoea and/or artificially induced acidosis are also reported (Lorenz and Gentile, 2014). On an average, in calves with clinical symptoms in postural, behaviour and palpebral reflex, serum values are elevated compared to those of animals without these clinical symptoms.

The FEEDAP Panel is not in the position to relate levels of D-lactate in the diets of pre-ruminants with serum D-lactate concentration and metabolic acidosis. In the absence of data, the FEEDAP Panel cannot conclude on a safe level of D-lactic acid for pre-ruminants. Consequently, no conclusions on the newly proposed maximum concentration of the additive can be drawn.

## 3.2.3. Safety for dogs, cats and minor species

No specific data were submitted for cats and dogs.

A safe level of lactic acid has been established only for pigs and cattle (50,000 mg LA/kg feed). Since a safe level has not been set for poultry, the FEEDAP Panel cannot extrapolate the conclusions reached in pigs and cattle to any other species.

#### 4. Conclusions

Based on the studies submitted in chickens for fattening and laying hens, no safe concentration of lactic acid and calcium lactate in complete feed for these species could be identified.

Owing to the absence of data on tolerated dietary levels of D-lactic acid, no conclusion on the safety of lactic acid in milk replacer for pre-ruminants is possible.

Since a safe concentration of lactic acid (and calcium lactate) was established only for pigs and cattle, and not for a third major animal species, no extrapolation to any other species is possible.

#### Documentation provided to EFSA

- 1) Lactic acid and calcium lactate for all animal species. August 2016. Submitted by Acids Authorisation Consortium (ACIAC EEIG).

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## Abbreviations

ADI	acceptable daily intake
ALT	alanine transaminase
ANOVA	analysis of variance
AST	aspartate transaminase
CP	crude protein
DM	dry matter
EC	European Commission
FEEDAP	EFSA Panel on Additives and Products or Substances used in Animal Feed
JECFA	The Joint FAO/WHO Expert Committee on Food Additives
LA	lactic acid
LSD	least significant difference
ME	metabolisable energy
WHO	World Health Organization