Annex K: RP1052a - L-lysine monohydrochloride produced by Corynebacterium glutamicum as a feed additive for all animal species

Annex K: RP1052a - L-lysine monohydrochloride produced by Corynebacterium glutamicum (KCCM 80216 or KCTC 12307BP) as a feed additive for all animal species (Daesang Europe B.V.) (new)?

Background

Name of applicant:

Daesang Europe B.V.

Address of applicant:

Van Heuven Goedhartlaan 935

1181 LD

Amstelveen

The Netherlands

FSA/FSS Safety Assessment

FSA/ FSS has undertaken a safety assessment of application RP1052a for the use of L-lysine monohydrochloride produced by fermentation with *Corynebacterium glutamicum* (KCCM 80216 or KCTC 12307BP) as a feed additive for all animal species, from Daesang Europe B.V.

FSA/FSS has reviewed the EFSA opinions (EFSA Journal 2020;18(12):6334 and EFSA Journal 2020;18(12):6333) and confirm that they are adequate for UK considerations and therefore a full safety assessment of this application was not performed by FSA and FSS. Please see the earlier section titled ‘Our safety assessment process’ to understand how and when we make use of EFSA opinions.

It is the FSA/FSS opinion that L-lysine monohydrochloride additive, as described in this application, is safe and is not liable to have an adverse effect on the target species, worker safety, environmental safety and human health at the intended concentrations of use. The proposed terms of authorisation are set below.

Any relevant provisions of retained EU law

Under the requirements of the Regulation for feed additives:

1. Article 16 and point 1(d) of Annex III: Labelling and packaging of feed additives and premixtures

2. Article 21: Analytical methods have been verified by the European Reference Laboratory as used for the control of L-lysine monohydrochloride in animal feed as detailed in the EURL analytical method evaluation reports (FAD-2020-0008).

- Valid analytical methods exist for: the identification of L-lysine monohydrochloride in the feed additive
- the quantification of L-lysine in the feed additive, premixtures, feed materials, compound feed and water.

3. Annex IV: The general conditions of use must be complied with, where applicable for the individual feed additive authorisation

Proposed terms of authorisation

1: Additive details

Category	Details
Additive category	(3) Nutritional feed additives
Functional group	(c) Amino acids, their salts and analogues
Feed additive	L?lysine monohydrochloride
ID No	3c327
Target species	All animal species
Authorisation Holder	Daesang Europe B. V.
Authorisation period	10 years from the date of authorisation

2: Additive composition

Component???	Contents???
L-lysine monohydrochloride (technically pure)	Powder with a minimum of 78% L-lysine and a maximum moisture content of 1.5%.?

3: Characterisation / identification of the active substance

L-lysine monohydrochloride produced by fermentation with *Corynebacterium glutamicum* (KCCM 80216 or KCTC 12307BP).

- L-lysine monohydrochloride (C?H??ClN?O?)
- CAS no: 657-27-2
- EINECS no: 211-519-9

4: Conditions of use

Species or category of animal?	Maximum age?	Content of L-lysine monohydrochloride (mg/kg of complete feed with a moisture content of 12%)?
All animal species?	n/a	Minimum level: No minimum? Maximum level:?No maximum?

5: Other Provisions

1. The lysine content shall be indicated on the labelling of the additive.
2. L-lysine monohydrochloride (technically pure) may be placed on the market and used as an additive consisting of a preparation.

6: Analytical methods

For the identification of L-lysine monohydrochloride in the feed additive:

Food Chemical Codex "L-lysine monohydrochloride monograph".

For the quantification of lysine in the feed additive and premixtures containing more than 10% lysine:

Ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) – BS EN ISO 17180:2013.

For the quantification of lysine in premixtures, feed materials and compound feed:

Ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS) - Annex III, F of Retained EU Regulation 152/2009 (Determination of Amino Acids (Except Tryptophan)).

For the quantification of lysine in water:

The EURL considered the following methods for the potential determination of lysine in water (as for other authorised sources of lysine):

- Ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) - BS EN ISO 17180:2013.; or
- Ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS) - Annex III, F of Retained EU Regulation 152/2009 (Determination of Amino Acids (Except Tryptophane)).

Other relevant information (separate to terms of authorisation)

1: Supplementary information

- Feed additives are subject to UK health and safety legislation. The safety assessment identified no specified hazards.
- Major animal species and their subgroups are defined in Annex IV of Retained EU Regulation 429/2008.
- The FSA/FSS consider there is no basis to propose specific requirements for a post-market monitoring plan other than those established in Retained EU Regulation 183/2005 ‘Feed

Hygiene Regulation’ and Good Manufacturing Practice.