Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food on a request from the Commission related to the use of L-cysteine in foods intended for infants and young children

Question n° EFSA Q-2005-083

Adopted on 26 September 2006

SUMMARY

The Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food has been asked to evaluate the use of L-cysteine as a food additive in certain foodstuffs intended for infants and young children.

L-cysteine is a non-essential amino acid occurring in a wide variety of foods, in particular cereals. The EC Scientific Committee for Food (SCF) has previously evaluated the safety of L-cysteine and considered that its use as a food additive in the treatment of flour is toxicologically acceptable. It is not however included in the list of food additives permitted in foods for infants and young children, although it is listed in European Community legislation as a substance that may be used for nutritional purposes in processed cereal-based foods and foods for infants and young children and in infant formulae and follow-on formulae.

Application has been made for use of L-cysteine and its hydrochloride as flour treatment agent in biscuits for infants and young children, at a level of 1 g/kg. Biscuits for infants and young children are required to have a suitable composition, including a controlled content of sugar and fat. However biscuit recipes with a low fat content have increased brittleness, with an associated risk of choking and/or suffocation due to breakage of the biscuit in the child’s mouth. The function of L-cysteine in the intended application is to act as a dough improver to control the texture of the final product.

The estimated intake of L-cysteine by infants aged 3 – 12 months as a result of the consumption of 1-3 biscuits potentially containing the amino acid is considered to be very low in comparison with the intake provided by the remainder of the child’s diet. The intake of 6 mg L-cysteine from one baby biscuit baked from dough containing the amino acid represents 2 % of the estimated total intake of 296 mg cysteine per day from a typical varied infant diet. Two biscuits per day will, proportionately, represent 4% of the total intake, while three biscuits will represent 6%.

The Panel concludes that the use of L-cysteine in processed cereal-based foods and foods (specifically baby biscuits) for infants and young children for technological purposes is of no safety concern. The Panel considers that the proposed use of L-cysteine to improve the texture of biscuits for infants and young children is not incompatible with previous advice of the SCF, that the addition of amino acids to foods intended for infants and young children.
should only be permitted for the purpose of improving the nutritional value of the foodstuff, given its intended application in achieving a product of suitable nutritional composition including a controlled content of sugar and fat.

KEY WORDS

E 920, L-cysteine, CAS 52-90-4, L-cysteine hydrochloride, flour treatment agent, foods for infants and young children.

BACKGROUND

L-cysteine is a non-essential amino acid occurring in a wide variety of foods, in particular cereals. The EC Scientific Committee for Food (SCF) evaluated the safety of L-cysteine in 1990 and considered that its use as a flour treatment agent was toxicologically acceptable provided its addition to food does not give rise to a nutritional imbalance of amino acids (SCF, 1991). L-cysteine is listed in Annex I of Directive 95/2/EC on food additives other than colours and sweeteners, with a footnote indicating that it may only be used as a flour treatment agent. It is not however included in Annex VI of the Directive, the list of food additives permitted in foods for infants and young children.

L-cysteine is also listed in European Community legislation as a substance that may be used for nutritional purposes in processed cereal-based foods and foods for infants and young children (Directive 96/5/EC, Annex IV), in infant formulae and follow-on formulae (Directive 91/321/EC, Annex III), and also as a nutritional substance in foods intended for particular nutritional uses (Directive 2001/15/EC). These Directives specify that the addition of amino acids to foods intended for infants and young children is permitted solely for the purpose of improving the nutritional value of the foodstuff and only in the proportions necessary for that purpose. The opinions of the Scientific Committee for Food on which this general provision is based did not specify the reason for this recommendation (SCF, 1983, 1991)

The European Commission has now received a request to extend the authorisation for L-cysteine as a food additive to permit its use in certain foodstuffs intended for infants and young children.

TERMS OF REFERENCE

In accordance with Article 29 (1) (a) of Regulation (EC) No 178/2002, the European Commission asks the European Food Safety Authority to provide a scientific opinion on the use of L-cysteine in processed cereal-based foods and foods for infants and young children for technological purposes. The Commission also requests that the European Food Safety Authority advise whether such a use of L-cysteine is incompatible with the previous advice from the Scientific Committee for Food, which recommended that the use of amino acids should solely be for the purpose of improving the nutritional quality of foods intended for infants and young children.
ASSESSMENT

Chemistry

L-cysteine, synonym (R)-2-amino-3-mercaptopropanoic acid, CAS 52-90-4, is a sulphur-containing amino acid, m. wt. 121.16. The same E-number, E 920, covers both L-cysteine and its hydrochloride, and the two substances are used interchangeably in food applications.

Specifications

Specifications for food-grade L-cysteine and L-cysteine hydrochloride are laid down in Directive 2000/63/EC

Case of need and proposed uses

The petitioner has made application for use of L-cysteine, L-cysteine hydrochloride or its monohydrate as a flour treatment agent in biscuits for infants and young children, at a level of 1g/kg. Biscuits for infants and young children are required to have a suitable composition, including a controlled content of sugar and fat, in accordance with Annex I of Directive 96/5/EC. However biscuit recipes with a low fat content have increased brittleness, with an associated risk of choking and/or suffocation due to breakage of the biscuit in the child’s mouth. The function of cysteine as a flour treatment agent in water-based doughs such as biscuit recipes is the reduction of disulphide bonds in gluten, thus acting as a dough improver, controlling the rheological properties of the dough and the texture of the final product.

Exposure

According to the petitioner, the use of L-cysteine at a level of 1g/kg in biscuits would result in a level of 6 mg L-cysteine in a 6 g. biscuit, or 12 mg L-cysteine in 2 biscuits.

The SCF in his Opinion on the Revision of Essential Requirements of Infant Formulae and Follow-on Formulae (SCF, 2003), in characterising the typical amino acid pattern for human milk protein, proposed a value of 2.1 g. cysteine/100 g protein. Based on a protein content of 12 g/litre in breast milk, it can be estimated that a 3-month old child consuming 700 ml milk per day will have an intake of 176 mg cysteine. The SCF recommended that infant formulae should be designed so that a 3-month old child consuming between 650 and 800 ml formula has an intake of 204 mg L-cysteine per day. It has been estimated that slightly older infants (8 months of age) consuming a typical menu containing infant milk, infant cereals, meat and pasta have an intake of approximately 290 mg cysteine per day (Arsan et al., 2003), while an American study has estimated that children aged between 7 and 12 months have an average daily intake of 390 mg cysteine (US National Academy of Sciences, 2005).
Table 1. Estimated dietary intakes of L-cysteine by infants

<table>
<thead>
<tr>
<th>Age group</th>
<th>Diet</th>
<th>Daily Intake of L-cysteine</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 months</td>
<td>Breast milk (700 ml/day)</td>
<td>176 mg</td>
</tr>
<tr>
<td>3 months</td>
<td>Formula</td>
<td>204 mg (recommended)</td>
</tr>
<tr>
<td>8 months</td>
<td>Varied infant diet (infant milk, infant cereals, meat and pasta)</td>
<td>290 mg</td>
</tr>
<tr>
<td>7 – 12 months</td>
<td>Varied infant diet</td>
<td>390 mg</td>
</tr>
</tbody>
</table>

The intake of 6 mg L-cysteine from one baby biscuit baked from dough containing the amino acid represents 2% of the total intake of 296 mg cysteine per day (including the contribution from the biscuit) estimated for an 8 month infant (Arsan et al., 2003). Two biscuits per day will, proportionately, represent 4% of the total intake, while three biscuits will represent 6%. The intake of 12 mg represented by 2 biscuits is the equivalent of the dietary intake from approximately 50 ml of follow-on milk, or 5 g of infant cereals (98% wheat flour), 4 g of pure beef or 4 g of pasta, typical components of a varied diet for an infant aged 8 months that contribute to the total intake of 296 mg cysteine per day estimated by Arsan et al. The Panel recognised that fruit and vegetables are also sources of L-cysteine in the infant’s diet.

Existing authorisations and evaluations

L-cysteine and L-cysteine hydrochloride are permitted food additives under Directive 95/2/EC and may also be used for nutritional purposes in processed cereal-based foods and foods for infants and young children (Directive 96/5/EC, Annex IV), in infant formulae and follow-on formulae (Directive 91/321/EC, Annex III), and also as a nutritional substance in foods intended for particular nutritional uses (Directive 2001/15/EC).

The SCF for Food evaluated the safety of L-cysteine in 1990 and considered that its use as a flour treatment agent was toxicologically acceptable provided its addition to food does not give rise to a nutritional imbalance of amino acids (SCF, 1991).

The SCF also concluded that the addition of amino acids to foods intended for infants and young children should be permitted solely be for the purpose of improving the nutritional value of the foodstuff and only in the proportions necessary for that purpose, without specifying the reason for this recommendation (SCF, 1983, 1991).

In addition, the Joint FAO/WHO Expert Committee (JECFA) has evaluated L-cysteine as a flavouring agent (JECFA, 2004) while EFSA has evaluated the oxidised form of L-cysteine, L-cystine, also as a flavouring agent (EFSA, 2006).

Toxicological data

Toxicological data on L-cysteine have not been provided by the petitioner, and the present application relies on the evaluations of its use as a flour treatment agent by the SCF (SCF, 1983, 1991) and its use as a flavouring agent by JECFA (JECFA, 2004). The evaluation by EFSA of L-cystine as a flavouring agent (EFSA, 2006) was also considered relevant, as the two amino acids are interconvertable via redox cycling.
In relation to use as a flour treatment agent, SCF concluded that the contribution to the total dietary intake of L-cysteine from use in bakery products would be insignificant, and therefore considered its use for flour treatment toxicologically acceptable. In relation to use as a flavouring agent, JECFA concluded that use of L-cysteine as a flavouring agent was of no safety concern, given that the substance is a macronutrient and normal component of protein, and, as such, human exposure through food would be orders of magnitude higher than the anticipated exposure from use as a flavouring agent. EFSA, in evaluating L-cystine concluded that its use as a flavouring agent, would not give rise to safety concerns at the levels of intake estimated on the basis of the Maximised Survey-derived Daily Intake (MSDI) approach, providing an estimated intake of 2.4 µg/capita/day (EFSA 2006). The estimated intake based on the modified Theoretical Added Maximum Daily Intake (mTAMDI) was 23 mg/person/day and EFSA concluded that more reliable exposure data are required in relation to L-cystine as a flavouring agent. This exposure information is included here for completeness but is not considered to be relevant to the evaluation of the proposed use as a flour treatment agent in processed cereal-based foods and foods for infants and young children.

DISCUSSION

The safety of L-cysteine has been evaluated by several expert bodies, and no toxicological concern has been expressed in relation to its use as a flour treatment agent, for nutritional purposes in processed cereal-based foods and foods for infants and young children, in infant formulae and follow-on formulae, as a nutritional substance in foods intended for particular nutritional uses and also as a flavouring agent. However, in relation to uses in infant formulae and follow-on formulae and in processed cereal-based foods and foods for infants and young children, the Scientific Committee for Food concluded that the addition of amino acids to foods intended for infants and young children should be permitted solely for the purpose of improving the nutritional value of the foodstuff and only in the proportions necessary for that purpose.

The current application relates to the use of L-cysteine as a food additive in biscuits for infants and young children for technological purposes. The intake of L-cysteine from such biscuits was estimated by the Panel to be low in comparison with the intake provided by the remainder of the diet consumed by a typical 8-month old infant, on the basis of a daily consumption of 1 – 3 biscuits. The inclusion of this additional source of L-cysteine in the diet does not give rise to concern on safety grounds.

In asking EFSA to provide a scientific opinion on the use of L-cysteine in processed cereal-based foods and foods for infants and young children for technological purposes, the Commission also requested that the European Food Safety Authority advise whether such a use of L-cysteine is incompatible with the previous advice from the Scientific Committee for Food.

The Panel endorses the view of the SCF that the use of amino acids in foods intended for infants and young children should primarily be for the purpose of improving the nutritional quality of those foods. The Panel considers that the proposed use of L-cysteine to improve the texture of biscuits for infants and young children is not incompatible with the advice of the SCF, given its intended application in achieving a product of suitable nutritional composition including a controlled content of sugar and fat.
CONCLUSION

The Panel concludes that the use of L-cysteine in processed cereal-based foods and foods (specifically baby biscuits) for infants and young children for technological purposes is of no safety concern. The Panel considers that the proposed use of L-cysteine to improve the texture of biscuits for infants and young children is not incompatible with previous advice of the SCF, that the addition of amino acids to foods intended for infants and young children should be permitted solely for the purpose of improving the nutritional value of the foodstuff, given its intended application in achieving a product of suitable composition, including a controlled content of sugar and fat.

DOCUMENTATION PROVIDED TO EFSA

Dossier on L-cysteine submitted by Bledina Danone

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