

## SCIENTIFIC OPINION

### Statement on the evaluation of the new information provided on the food additive ethyl lauroyl arginate<sup>1</sup>

#### EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS)<sup>2</sup>

European Food Safety Authority (EFSA), Parma, Italy

#### ABSTRACT

Following a request from the European Commission to the European Food Safety Authority (EFSA), the Panel on Food Additives and Nutrient Sources added to Food (ANS) was asked to determine whether the new information provided on ethyl lauroyl arginate constitutes new scientific evidence compared to that originally submitted and considered in the AFC Panel opinion, and to evaluate the extent to which this additional information addresses the concerns and uncertainties expressed in the opinion of the AFC Panel. The ANS Panel has considered the opinions of three experts on the white blood cell data from a series of toxicity studies with ethyl lauroyl arginate, which conclude separately that the haematological findings are toxicologically not significant. The Panel concludes that the new information provided is the expression of the opinions of three individual experts presenting a re-examination of some of the original results provided in the application dossier for ethyl lauroyl arginate and that it does not contain new scientific evidence. The Panel concludes that scientific evidence of a plausible mechanism for the alterations in white blood cell counts has not been provided and therefore concludes that the concerns and uncertainties expressed in the opinion of the AFC Panel have not been addressed by the new information provided.

#### KEY WORDS

Ethyl lauroyl arginate, food additive, lauramide arginine ethyl ester, CAS Registry Number 60372-77

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1 On request from the European Commission Question No EFSA-Q-2009-00609, adopted on 24 September 2009.

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## **BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION**

Following a request from the Health and Consumers Directorate-General, the EFSA Scientific Panel on Food additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC) provided an opinion on 17<sup>th</sup> April 2007 on a new food additive, ethyl lauroyl arginate. In this opinion the Panel established an Acceptable Daily Intake (ADI) for the new food additive and expressed its opinion on the potential exposure from the proposed uses in food. The Health and Consumers Directorate-General has subsequently received from the original applicant a series of three expert opinions re-examining the findings on white blood cell counts in the original studies provided by the applicant.

Given that the information provided by the applicant is not new data, but appears to be a re-examination of the original results, the Commission considers that it is not appropriate to request at this stage a new scientific opinion. However, the Commission would like to request technical assistance from EFSA as to whether this new information would justify a full re-evaluation.

## **TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION**

In accordance with Article 31 of Regulation (EC) No 178/2002, the European Commission asks the European Food Safety Authority to provide technical assistance in relation to a potential re-evaluation of ethyl lauroyl arginate.

The European Food Safety Authority is asked to:

- Determine whether this new information constitutes new scientific evidence compared to that originally submitted and considered in the AFC Panel opinion.
- Evaluate the extent to which this additional information addresses the concerns and uncertainties expressed in the opinion of the AFC Panel.

## **ACKNOWLEDGEMENTS**

The European Food Safety Authority wishes to thank R.A. Woutersen for his contribution to the preparation of this opinion.

## EVALUATION

### 1. Introduction

Following a request from the European Commission to the European Food Safety Authority (EFSA), the Panel on Food Additives and Nutrient Sources added to Food (ANS) was asked to determine whether the new information provided on ethyl lauroyl arginate constitutes new scientific evidence compared to that originally submitted and considered in the AFC Panel opinion, and to evaluate the extent to which this additional information addresses the concerns and uncertainties expressed in the opinion of the AFC Panel.

### 2. Evaluation

The Panel notes that the new information provided is the expression of the opinions of three individual experts presenting a re-examination of some of the original results provided in the application dossier for ethyl lauroyl arginate. The Panel concludes that the additional information provided does not contain new scientific evidence.

In its opinion adopted on 17 April 2007, the EFSA Scientific Panel on Food additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC Panel) noted that two 13-week studies and the 52-week study in rats report consistent effects on white blood cell counts and concluded that the effects on white blood cell counts cannot be disregarded because they are seen in different rat strains and in different sexes in two 90-day studies and in one 52-week study (EFSA, 2007).

The AFC Panel established an ADI of 0.5 mg ethyl lauroyl arginate/ kg bw/day based on the effects on white blood cell counts observed in two 90-days studies and a 52-week study in rats.

The ANS Panel has considered the expert opinions of R.R. Maronpot, G. Brown and G. Escobar on the white blood cell data from a series of toxicity studies with ethyl lauroyl arginate originally provided with the application dossier for this food additive.

These three experts conclude separately that the haematological findings are toxicologically not significant, based on the following considerations:

- The observed effects on the white blood cell parameters are inconsistent both within and between the studies considered and did not demonstrate a dose-effect relationship.
- The effects on the white blood cells were not accompanied by histopathological changes in any of the studies considered.

The Panel is of the opinion that, given the fact that the alterations in white blood cell counts were found consistently in different strains of rats and in different sexes in two 90-day studies and in a 52-week study, the toxicological relevance of these findings cannot be assessed as long as the mechanism leading to these abnormalities is not elucidated.

The Panel notes that hypotheses for the possible mechanism(s) underlying the reduction in white blood cells were provided by the expert opinions, but that these were speculative and not consistent. Therefore, the Panel concludes that scientific evidence of a plausible mechanism for the alterations in white blood cell counts has not been provided and that the concerns and uncertainties expressed in the opinion of the AFC Panel have not been addressed by the new information provided.

## **CONCLUSIONS**

The Panel concludes that the new information provided is the expression of the opinions of three individual experts presenting a re-examination of some of the original results provided in the application dossier for ethyl lauroyl arginate. The Panel concludes that the new information provided does not contain new scientific evidence.

The Panel concludes that scientific evidence of a plausible mechanism for the alterations in white blood cell counts has not been provided and therefore concludes that the concerns and uncertainties expressed in the opinion of the AFC Panel have not been addressed by the new information provided.

## **DOCUMENTATION PROVIDED TO EFSA**

1. Letter dated 29 July 2008. LAMIRSA, Terrassa, Spain
2. Expert opinion of G. Brown, Huntingdon, UK
3. Expert opinion of G. Escolar, Barcelona, Spain
4. Expert opinion of R.R. Maronpot, Raleigh, North Carolina, USA

## **REFERENCES**

EFSA, 2007. Opinion of the Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC) on the use of ethyl lauroyl arginate as a food additive. The EFSA Journal (2007) 511, 1-27.

## Glossary / Abbreviations

AFC	Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food
ANS	Panel on Food Additives and Nutrient Sources added to Food
EC	European Commission
EFSA	European Food Safety Authority