Tocopherols (E 306 – 309) used in foods for infants below 16 weeks of age

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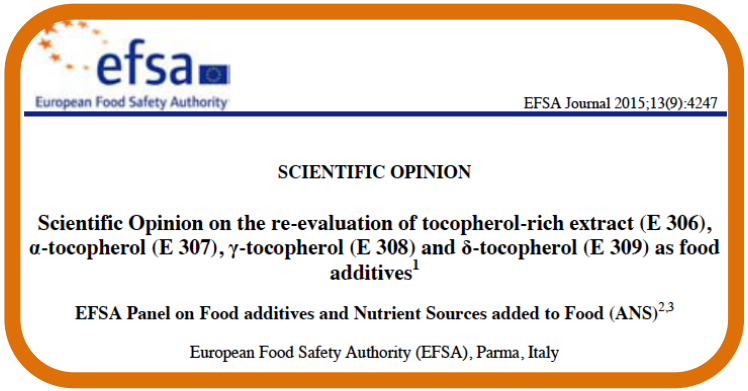
efsa
European Food Safety Authority

Previous evaluations



efsa
European Food Safety Authority

EFSA Journal 2015;13(9):4247

SCIENTIFIC OPINION

Scientific Opinion on the re-evaluation of tocopherol-rich extract (E 306), α-tocopherol (E 307), γ-tocopherol (E 308) and δ-tocopherol (E 309) as food additives[1]

EFSA Panel on Food additives and Nutrient Sources added to Food (ANS)[2,3]

European Food Safety Authority (EFSA), Parma, Italy

SCF, 1989: As FAs acceptable; exposure much lower; toxicologic equivalence - chemical and biological similarities

SCF 2003: UL 300 mg/day for vit. E (effects on blood clotting)

JECFA 1973: ADI 0 - 2 mg/kg bw; limitations of tox. database; α-tocopherol a nutrient

JECFA 1987: group ADI of 0.15-2 mg/kg bw/day for dl-α-tocopherol and d-α tocopherol

EFSA ANS Re-evaluation 2015

Observations

- Levels of As, Pb and Hg in specifications (CR EU No 231/12)
- Stability:
  - Ts are stable in foods but oxidation may occur (exposure to air, heat, acids, alkalis, metal ions)
  - Decrease in TS content during food processing due to oxidation or thermal degradation
- Chemical and biological similarities (SCF 1989)
- ADME:
  - α-tocopherol: biological activity
  - "Worst case": re-secretion to plasma by the liver (maintaining plasma concentration and prolonging time in the plasma before elimination)
- Toxicological DB:
  - insufficient studies on reproduction and developmental endpoints
  - no multigeneration studies available

Conclusion of the ANS Panel in 2015

- The use of tocopherols E 306 – E 309 as FAs would not be of safety concern at the reported uses and use levels.
- The Panel considered that use levels of tocopherols (E 306-E 309) in food for infants would require a specific risk assessment in line with the recommendations given by JECFA (1978) and the SCF (1998) and endorsed by the Panel.

Considerations

- Vit E consumed via food
- Essential nutrient
- No indication of
  - genotoxicity
  - carcinogenicity
- No adverse effects (H&A)
  - effect on blood cloting only at high doses
- Exposure vs. UL

Recommendation

- Re-assessment of apropriateness of the read-accross from α-tocopherol to the other Ts when new data available

Data needs to address previous conclusions and recommendations

Technical data

- analytical data on current levels of lead, mercury and arsenic in commercial samples of the food additives;
- the lowest technologically achievable level for lead, mercury and arsenic in order to adequately define their maximum limits in the specifications;
- analytical data on the composition of tocopherol-rich extract in commercial samples of the food additive E 306 in accordance with the Guidance on food additive evaluation;

Toxicological data

- information to address the reproductive and developmental endpoints with respect to all uses including information on the tested material

Data need to perform RA for uses in foods for infants below 16 weeks

Technical data

- information on particular specification requirements for identity and the purity of E 306, E 307, E 308 and E 309 (e.g. content of toxic elements)
- analytical data on impurities in the final special formulae for infants below 16 weeks of age when no legal limit has been established in these foods
- data demonstrating the absence of *Cronobacter (Enterobacter) sakazakii*
- information on the levels of use of E 306, E 307, E 308 and E 309 alone or in combination with other tocopherols (indication of food additive name and level of use);
- information on the fate and the reaction products of E 306, E 307, E 308 and E 309

Data needs to perform RA for uses in foods for infants below 16 weeks

Toxicological data (I)

- an Extended One Generation Reproductive Toxicity Study (EOGRTS) in accordance with OECD TG 443 with E 307, E 308, E 309 and E 306
- however, data requirement can be reduced based on a justified read across approach between the different tocopherols or by other relevant scientific information

Data needs to perform RA for uses in foods for infants below 16 weeks

Toxicological data (II)

- clinical data to assess the safety of E 306, E 307, E 308 and E 309 in FC 13.1.1 and FC 13.1.5.1
- post-marketing surveillance reports on undesired and adverse reactions
- published and unpublished case reports (e.g. available nutrivigilance data)

Thank you