SCIENTIFIC OPINION

EFSA Journal

ADOPTED: 20 June 2017

doi: 10.2903/j.efsa.2017.4909

Re-evaluation of xanthan gum (E 415) as a food additive

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Abstract

The Panel on Food Additives and Nutrient Sources added to Food (ANS) provides a scientific opinion re-evaluating the safety of xanthan gum (E 415) as food additive. Following the conceptual framework for the risk assessment of certain food additives re-evaluated under Commission Regulation (EU) No 257/2010, the Panel considered that adequate exposure and toxicity data were available. Based on the reported use levels, a refined exposure of up to 64 mg/kg bw per day in children for the general population, 38 mg/kg bw per day for children consumers only of food supplements at the high level exposure and 115 mg/kg bw per day for infants consuming foods for special medical purposes and special formulae (FSMPs), were estimated. Xanthan gum (E 415) is unlikely to be absorbed intact and is expected to be fermented by intestinal microbiota. No adverse effects were reported at the highest doses tested in chronic and carcinogenicity studies and there is no concern with respect to the genotoxicity. Repeated oral intake by adults of xanthan gum up to 214 mg/kg bw per day for ten days was well tolerated, but some individuals experienced abdominal discomfort, an undesirable but not adverse effect. The Panel concluded that there is no need for a numerical ADI for xanthan gum (E 415), and that there is no safety concern for the general population at the refined exposure assessment of xanthan gum (E 415) as food additive. Considering the outcome of clinical studies and post-marketing surveillance, the Panel concluded that there is no safety concern from the use of xanthan gum (E 415) in FSMPs for infants and young children at concentrations reported by the food industry. The current re-evaluation of xanthan gum (E 415) as a food additive is not considered to be applicable for infants under the age of 12 weeks.

Keywords: xanthan gum, E 415, CAS number: 11138-66-2, food additive

Requestor: European Commission

Question number: EFSA-Q-2011-00514

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