

SCIENTIFIC OPINION

Scientific Opinion on the re-evaluation Tartrazine (E 102)¹

EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS)^{2, 3}

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

The Panel on Food Additives and Nutrient Sources added to Food provides a scientific opinion re-evaluating the safety of Tartrazine (E 102). Tartrazine has been previously evaluated by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 1966 and the EU Scientific Committee for Food (SCF) in 1975 and 1984. Both committees established an Acceptable Daily Intake (ADI) of 0-7.5 mg/kg bw/day. The Panel was not provided with a newly submitted dossier and based its evaluation on previous evaluations, additional literature that became available since then and the data available following a public call for data. New studies included a study by Sasaki *et al.* from 2002 reporting effects on nuclear DNA migration in the mouse *in vivo* Comet assay, a study by McCann *et al.* from 2007 that concluded that exposure to a mixture including Tartrazine resulted in increased hyperactivity in 3-year old and 8- to 9-year old children and studies on neurodevelopment by Tanaka. The Panel notes that Tartrazine was negative in long-term carcinogenicity studies and that the effects on nuclear DNA migration observed in the mouse *in vivo* Comet assay are not expected to result in carcinogenicity. The Panel also concurs with the conclusion from a previous EFSA opinion on the McCann *et al.* study that the findings of the study cannot be used as a basis for altering the ADI, and additionally considered that the Tanaka study can also not be used as a basis for altering the ADI. The Panel concludes that the present database does not give reason to revise the ADI of 7.5 mg/kg bw/day. The Panel also concludes that at the maximum reported levels of use, refined intake estimates are below the ADI. The Panel concludes that Tartrazine appears to be able to elicit intolerance reactions in a small fraction of the exposed population. The Panel also notes that sensitive individuals may react to Tartrazine at dose levels within the ADI.

KEY WORDS

Tartrazine, FD&C Yellow No. 5, E 102, CAS 1934-21-0, 3-carboxy-5-hydroxy-1-(4'-sulphophenyl)-4-(4'-sulphophenylazo) pyrazole trisodium salt, food colouring substance.

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