1.10 Public summary

Applicant: Ingenious Ingredients, LP; 2560 King Arthur BLVD, Suite 124-74; Lewisville, TX 75056; USA

The subject of this application is the authorisation of paraxanthine (ENFINITY®), a methylxanthine. Paraxanthine is the main metabolite of dietary caffeine in humans, however, it has no history of use as food in the EU or elsewhere.

Paraxanthine is manufactured by chemical synthesis. As synthetic paraxanthine was not consumed to a significant degree in the EU before May 15, 1997, it is a novel food according to Regulation (EU) 2015/2283.

The identity of synthetic paraxanthine (1,7-dimethyl-3H-purine-2,6-dione) has been analytically verified. Analyses of the typical composition of five representative batches demonstrated the manufacturing consistency. Synthetic paraxanthine is an off-white to white powder with a high purity (at least 97 %). Levels of heavy metals, solvent and reaction residues as well as the microbial quality of the novel food ingredient are in-line with the requirements for food products.

The applicant intends to use paraxanthine as an alternative to caffeine in selected food categories, in particular functional drinks and food supplements at the same use levels as caffeine.

The target population for this novel food ingredient is the general population. Like caffeine, paraxanthine is not recommended for children, pregnant and lactating women. Final products containing it will be labelled respectively.

The anticipated daily intake (max. 95th) of synthetic paraxanthine in the target population group is 80 mg for adults. The intake would rise to 280 mg per day for adults if food supplements with a daily dose of 200 mg are consumed concomitantly.

As paraxanthine is not yet part of the human diet, no direct intake of paraxanthine from other sources is expected.

Studies on ADME have shown that paraxanthine is the main metabolite of caffeine and that both methylxanthines share the pathways for metabolism and excretion in the human body.

To demonstrate the safety of synthetic paraxanthine, the applicant conducted tier-1 toxicity studies with paraxanthine. The results of the bacterial reverse mutation test (OECD 471), the *in-vitro* mammalian chromosomal aberration test (OECD 473) and the mammalian erythrocyte micronucleus test in rats (OECD 474) showed that synthetic paraxanthine is neither genotoxic nor mutagenic. As demonstrated by a 90-days subchronic toxicity study in rats (OECD 408), oral administration of synthetic paraxanthine at a daily dose of up to 300 mg/kg body weight is not toxic.

Synthetic paraxanthine was well-tolerated in human studies up to a daily dose of 200 mg for adults over a study period of 7 days.

Analogue to the safe daily intake levels for caffeine that have been proposed by EFSA (2015), the applicant considers maximum single doses of 200 mg and a habitual daily consumption of max. 400 mg synthetic paraxanthine safe for adults (excl. pregnant or lactating women).

Based on the provided data the applicant is of the opinion that:

- synthetic paraxanthine does not pose a safety risk to human health
- the intended uses of synthetic paraxanthine does not mislead the consumer
- synthetic paraxanthine is as safe as caffeine that is already marketed in the intended food categories in the EU and is not nutritionally disadvantageous

References to section 1.10 “Public summary”:

EFSA (2015). Scientific Opinion on the safety of caffeine. EFSA Journal *13*, 4102.