

Executive summary

Saraya Co., Ltd. is applying to Food Standards Australia New Zealand (FSANZ) to permit the use of luo han guo extract as a food additive, specifically as an intense sweetener.

Approval by FSANZ would require amendments to the Australia New Zealand Food Standards Code Schedule 15 – ‘Substances that may be used as food additives’ and Schedule 8 – ‘Food additive names and code numbers (for statement of ingredients)’.

Luo han guo are the fruit of a vine endemic to southern China, *Siraitia grosvenorii* (Swingle) C. Jeffrey. The dried fruit has been consumed in preparations as a traditional medicine in China for centuries. Luo han guo extract, which contains a higher concentration of the fruit’s sweet components (cucurbitane triterpene glycosides, known as mogrosides) was developed in the 1970s and 1980s, before commercial-scale production began in the 1990s for the Japanese market.

The extract is typically around 150 times the sweetness of sucrose and has specific available energy of 16 kJ/g. Therefore, at the maximum proposed concentration of use of 8000 mg/kg, it fulfils the technical function of an intense sweetener.

It is notable as an intense sweetener due to the lack of bitter aftertaste that is common with many other intense sweeteners, and its versatility when employed in a spoon-for-spoon sugar replacement product thanks to its heat stability and utility in cooking and baking.

Saraya believes there is value in approving luo han guo extract for use as an intense sweetener as it will: provide an alternative sweetener product to those that find other intense sweeteners unpalatable; potentially increase competition through marketplace diversity; provide greater international trade opportunities, particularly with China; and provide new market opportunities for Australian and New Zealand-based businesses, especially those that already produce luo han guo extract-containing products.

Luo han guo extract is currently approved for use as a food additive in the US, Canada, Japan and China. Regulations in China and Japan do not place restriction on the scope or level of use in foods as the extract is considered an existing food additive (at the time of regulations being introduced) with a demonstrated safe history of use. Health Canada performed an independent risk assessment and subsequently permitted the use of luo han guo extract up to 0.8% w/w measured as mogroside V—the major component of the extract. The USFDA has approved four GRAS (Generally Recognized As Safe)

determinations for loo han guo extract use as a food additive without further questions for the applicants.

The metabolic pathway of mogroside V has been determined by *in vivo* rat studies. Varying degrees of deglycosylation, hydroxylation, dehydrogenation, methylation and isomerisation result in the formation of other mogrosides and their aglycone—mogrol. Around 60% of mogroside V and its metabolites are directly excreted from the gastrointestinal tract, with the remaining portion being absorbed. Mogroside IIE, in particular, has been shown to accumulate in the heart, liver, spleen, lung and intestine, and it is suspected that it is this compound that plays a role in the pharmacological actions that loo han guo extract may achieve at concentrations above 100 mg/kg bw. These potential pharmacological actions include: liver-protection and blood glucose regulation functions, and anti-bacterial, anti-carcinogenic, anti-fatigue, anti-inflammatory, anti-allergenic and immunostimulatory effects.

The toxicity of loo han guo extract has been explored in numerous *in vivo* and *in vitro* studies, including acute toxicity, short-term toxicity, long-term toxicity, genotoxicity and mutagenicity studies. In all cases there were no observed adverse effects, establishing an NOAEL for each category of toxicity for both the extract itself and for mogroside V. The lowest (i.e. most restrictive) NOAEL of any category is 600 mg/kg bw for genotoxicity of mogroside V. All other NOAELs for mogroside V are above 1 g/kg bw. The NOAEL for acute toxicity of loo han guo extract is 10 g/kg bw.

Even at 600 mg/kg bw, a 150-fold safety factor exists over the highest estimated daily intake (EDI) for 90th percentile consumers given in any of the GRAS determinations submitted to the USFDA—3.86 mg/kg bw per day for a healthy child.

Conservatively assuming this highest EDI applies to a 75 kg individual, this would still only represent around the same intake of mogroside V as is contained in a single loo han guo (fruit), which is consistent with the consumption of loo han guo for traditional purposes in China. Given the centuries of demonstrated safe use at those levels, this strengthens the safety case of loo han guo extract and Saraya believes that approving the extract for use as food additive in Australia and New Zealand poses a very low risk.