

SUBMISSION FROM SA HEALTH

31 August 2018

Application A1158 Rosemary Extract as a food additive (antioxidant)

SA Health welcomes the opportunity to provide comment on this application. It is noted that this application has only one period of public comment. SA Health is concerned that before supporting this application for the approval of a new antioxidant that it should be assessed for public health and safety to the same minimum level as described in the FSANZ Application guidelines.

Concerns are related to,

1. being unclear whether the proponent have provided any or relevant safety studies associated with their proprietary extract.
2. the change in the paradigm of assessment for food additives typically from well characterised substance(s) to the assessment of poorly defined mixtures with limited supporting safety data (pg 76 Section 3.3 B Information related to the safety of the food additive; FSANZ Application Handbook).
3. whether a component based safety assessment for mixtures is appropriate in this case, particularly when plant extracts may result in combined exposures to individuals from various routes (e.g. oral, dermal etc) and potentiate different toxicological outcomes. This general comment is contextualised in reference to sensitivity reactions that may be observed in the use of particular herbal extracts in cosmetic preparations and the relevance of sensitivity reactions to food-based 'plant extract' exposures.
4. a broad interpretation of 'history of safe use' for the safety assessment purpose, i.e. the herb is safe, the flavouring extract (used in very low concentrations) is safe, therefore the concentrated extract (used at higher concentrations) is safe. A contrarian example is that of *Papaver somniferum* (the opium poppy seed); poppy seed as a food is deemed safe through tradition/history of use, poppy seed as a flavouring would be deemed safe through tradition of use (and low concentration), but to conclude that a poppy seed extract is safe or appropriate may not be correct without an appropriate assessment.
5. the conclusion of the risk assessment was based on a temporary ADI set by Joint FAO/WHO Expert Committee on Food Additives (JECFA). The

application indicated that the temporary status of the ADI is pending the outcomes of a toxicology study on the reproductive and developmental effects of carnosic acid plus carnosol. FSANZ has confirmed that these studies are nearing completion, with study results expected to be submitted to JECFA by the end of 2018. FSANZ stated that it may reconsider the safety of using rosemary extract as an antioxidant if the temporary ADI is amended by JECFA upon their evaluation of the reproductive and developmental study.

It is of concern that if FSANZ approves the rosemary extract and then has to change or remove this permission later this year that this may result in a food recall in Australia and New Zealand for all food products using rosemary extract. This would be a risk to public health and safety and a significant cost to the food industry and government to conduct a food recall. It would be more prudent to place a “stop clock” on approval of this new food additive pending the conclusion of JECFA decision on ADI later this year.

6. a final JECFA specification for rosemary extract is expected upon completion of the assessment of the reproductive and developmental toxicology data. Again it would be prudent to “stop clock” the application until the JECFA specification is finalised.
7. the dietary exposure assessments were undertaken using FSANZ’s dietary modelling computer program, Harvest4. The food category codes used by the applicant were based on the Australia New Zealand Food Classification System (ANZFCS) in Standard 1.3.1 – Food Additives of the Code and its related Schedules. However, the food classification codes in Harvest can vary and may also be split into sub-groups. The categories selected reflect the description of the foods requested by the applicant, not the food additive codes. Although outside the scope of this application, FSANZ should consider when reviewing Standard 1.3.1 aligning its food category codes of the ANZFCS to Harvest, so that a more accurate modelling can be achieved.