

Application to Amend the Australia and
New Zealand Food Standards Code.

Addition of the Food Additive Rosemary
Extract (INS 392) to Schedule 8 and
Schedule 15.

Executive Summary

An application is made to FSANZ to amend the Food Standards Code to add Rosemary Extract (INS 392) to the following schedules of the FSANZ Food Standards Code:

- Schedule 8: Food additive names and code numbers (for statement of ingredients)
- Schedule 15: Substances that may be used as food additives

This application refers to rosemary extracts prepared using acetone or ethanol solvent extraction and complies with monographs of the JECFA (draft) and the Food Chemicals Codex (FCC 10). The application requests permission for the addition of rosemary extracts in a range of food categories.

Rosemary extracts are derived from *Rosmarinus officinalis* L. and contain several compounds which have been shown to exert antioxidative functions. Although the entire rosemary (*Rosmarinus officinalis* L.) plant, excluding the woody portions, may be used, it is normally only the leaves, that are commonly used as a culinary herb, flavouring agent and naturally occurring antioxidant. Rosemary extracts are increasingly employed not only to provide flavour but also as natural alternatives to synthetic antioxidants for the stabilisation of oxygen-sensitive foods. The antioxidative function is due to several components in the rosemary extracts, which belong mainly to the classes of phenolic acids, flavonoid diterpenoids and triterpenes

The antioxidative function of rosemary extracts helps to stabilise product formulations thus providing longer shelf-life. Rosemary extracts are naturally derived extracts and thus provide a benefit to consumers seeking more 'natural' ingredients in their food products

Rosemary extract E 392 is approved in the EU additives regulation No. 1129/2011. It was evaluated by the European Food Safety Authority (EFSA) in 2008 (EFSA, 2008) and then again in 2015 to extend its uses to fat based spreads (EFSA, 2015). Rosemary extract is also approved for use as a food additive in Japan, China and Singapore. Rosemary extract is allowed in the United States as a flavour although it appears on some food labels as a preservative. The applicant is pursuing a self-affirmed GRAS position for rosemary antioxidant extract that is based upon the EU and JECFA evaluations

At the Forty-fifth Session of CCFA in 2013 (FAO/WHO, 2013b), it was concluded that although rosemary extract had been assigned an INS number (392), it had not yet been evaluated by Joint FAO/WHO Expert Committee on Food Additives (JECFA). The Committee evaluated rosemary extract at the 82nd meeting at the request of CCFA. The Committee concluded that there are sufficient data to establish an acceptable daily intake (ADI) for rosemary extract prepared according to the specifications established. The Committee established a temporary ADI of 0–0.3 mg/kg bw for rosemary extract, expressed as carnosic acid plus carnosol, on the basis of a NOAEL of 64 mg/kg bw per day, expressed as carnosic acid plus carnosol, the highest dose tested in a short-term toxicity study in rats, with application of a 200-fold uncertainty factor. The overall uncertainty factor of 200 incorporates a factor of 2 to account for the temporary designation of the ADI. The Committee made the ADI temporary pending the submission of studies to elucidate the potential developmental and reproductive toxicity of the rosemary extract under consideration. An additional uncertainty factor to account for the lack of a chronic toxicity study was not considered necessary based on the absence of adverse effects in the short-term toxicity studies at doses up to and including the highest dose tested. The temporary ADI applies to rosemary extract that meets the specifications prepared at the present meeting. The temporary ADI will be withdrawn if the required data are not provided by the end of 2018.

The Committee noted that the dietary exposure estimates for rosemary extract for high consumers in the European and USA populations of 0.09–0.81 mg/kg bw per day (expressed as carnosic acid plus carnosol) may exceed the upper bound of the temporary ADI by up to 2.7-fold (for young children at the top end of the range of estimated dietary exposures). Based on the conservative

nature of the dietary exposure assessments, in which it was assumed that all foods contained rosemary extracts at the maximum use level, the Committee concluded that this exceedance of the temporary ADI does not necessarily represent a safety concern. The Committee requested that data on typical use levels in foods be provided by the end of 2018 in order to refine the dietary exposure estimates.

These studies requested by JECFA are currently being undertaken and will be submitted to JECFA by the end of 2018 as requested. The applicant, however, does not believe that waiting for these additional studies should hold up the progression of this application for a number of reasons. EFSA evaluated rosemary extract in 2008 and again in 2015. On neither occasion did EFSA raise any safety issues. EFSA did not set an ADI, but concluded the use of rosemary extract does not pose a risk to health. Rosemary has been used as an herb in cooking for hundreds of years without any indication that it causes developmental or reproductive toxicity. It has been available, as an antioxidant, in the EU since 2009 and as a flavour, globally, for many decades prior without any indication or report of it causing developmental or reproductive toxicity. However, considering that rosemary extract may have more concentrated levels of constituents than found in rosemary herb, the applicant has sought to address this, while waiting for the additional studies requested by JECFA to be completed, by reducing the number of food categories being sought for the use of rosemary extract as compared to the EU. Further, in some food categories the applicant has reduced the maximum permitted level sought compared to the EU. These measures will reduce the overall exposure of rosemary extract thus providing a further level of safety.