Draft EFSA Scientific Opinion on the evaluation of the safety of preparations from the fruits of sweet and bitter fennel (Foeniculum vulgare Mill. and Foeniculum piperitum (Ucria) C.Presl)

Risk characterisation and Conclusions (Sections 3.8 and 5)

In this guide

51. In the current draft opinion, EFSA followed its own guidance documents for the assessment of genotoxic carcinogens, specifically, the risk assessment acknowledged that chemical substances which were genotoxic carcinogens should not purposefully be added to foods or the food chain but that if the substance was unavoidable i.e., part of the typical diet, and if data was available, it was possible to qualify the safety concern based on an MoE approach.

52. Based on the whole population exposure assessment scenario, high consumption (P90 and P95) resulted predominantly in MoEs of <10,000 (range: 712-9,901 at the P95, median: 4,013) for *p*-allylalkoxybenzenes, whilst average consumption resulted in MoE generally >10,000, except for infants, toddlers and other children in some Member States including Cyprus, Germany, France, Italy and Portugal. Please see Appendix A.1 of the draft EFSA opinion for a list of MoEs for total *p*-allylalkoxybenzenes exposure in the whole population in EU Member States.

53. In the whole population scenario, consumption of fennel fruit infusions in Germany and Poland were significant contributors to total *p*-allylalkoxybenzene in infants, toddlers, and in addition in other children for Germany only. These exposures are in line with exposures of scenario 2, demonstrating that fennel fruit infusion could contribute significantly to total *p*-allylalkoxybenzene exposure in children up to 10 years of age and the elderly (see paragraph 50). EFSA noted there were insufficient data within EFSA's food consumption database to create exposure scenarios for other fennel fruit preparations; thus, it is uncertain how much they could potentially contribute to total dietary *p*-allylalkoxybenzene exposure.

54. EFSA noted that in children aged ≥3 to <10 years (other children), removing exposure to *p*-allylalkoxybenzenes from fennel fruit infusions generally led to increased MOEs at the P90 and P95 intake distribution. In this group, MOEs for P90 values ranged from 2,776 to 16,653, while MOEs for P95 values ranged from 1,462 to 7,710.

55. EFSA concluded that "the exposure to fennel fruit infusions in infants and young children and to food supplements with fennel fruit preparations in all population groups containing detectable amounts of estragole assessed through

advanced and validated analytical procedures falls under the consideration that substances that are both genotoxic and carcinogenic should not be deliberately added to foods or used in the food chain (EFSA Scientific Committee, 2005, 2012).”

56. EFSA noted that *p*-allylalkoxybenzenes have been reported to cross the placenta and form DNA adducts in the foetus. They have also been detected in breast milk following maternal consumption and to have subsequently been carcinogenic in the offspring of mice (Vesselinovitch et al., 1979). Therefore, EFSA concluded that intake of foods containing genotoxic and carcinogenic compounds including estragole-containing fennel fruit preparations during pregnancy and lactation may pose health risks to both the unborn child and the newborn.

57. In adolescents and adults, fennel fruit infusions containing estragole generally contributed only a small proportion to the overall exposure to *p*-allylalkoxybenzenes. However, EFSA noted that regardless of total *p*-allylalkoxybenzenes intake, reducing estragole exposure still helps to mitigate the health risks associated with genotoxic carcinogens.