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)

Exposure assessment (Section 3.7)

In this guide

This is a paper for discussion. This does not represent the views of the Committee and should not be cited.

44. Occurrence data on *p*-allylalkoxybenzenes in food were collected by systematic review and a call for data as described under Section 2 ‘Data and Methodologies’ of the draft EFSA opinion.

45. Please see Subsection 2.2.2 for more detail on the methodology of the exposure assessment, however in summary, two exposure scenarios were considered, a) a general chronic dietary exposure scenario in the whole population and b) a scenario to estimate the exposure in fennel fruit infusion consumers only. To better estimate the higher percentiles of exposure, consumption of unspecified herbal blends were assumed to contain dried fennel fruits.

46. The chronic dietary exposure scenario for the whole population showed that the highest average exposure and highest 95^{th} percentile (P95) exposure to *p*-allylalkoxybenzenes were in toddlers (4.1 and 21.9 µg/kg bw, respectively), followed by other children (3.9 and 14.7 µg/kg bw, respectively) and infants (3.7 and 13.8 µg/kg bw, respectively). A summary of these exposures is provided in Table 8 of the draft EFSA opinion.

47. In the whole population exposure scenario most, estimated mean exposures were greater than a margin of exposure (MoE) of 10,000, with the exception of infants (12 months), toddlers (≥1 to 3 years) and other children (≥3 to 10 years) in a few Member States. At the higher percentile exposures (P90 and P95) the MoE was more often 10,000 (range: 712-9,901 at the P95, median: 4,013) especially in younger age groups. A summary of the mean, P90 and P95 MoEs is presented in Table 9 of the draft EFSA opinion.

48. In the whole population scenario, the most frequently consumed food groups across dietary surveys and age groups contributing to the exposure were aromatic herbs, spices, fruits and vegetables, and cola-type drinks. In this scenario, the consumption of fennel fruit infusions also had a relevant contribution to *p*-allylalkoxybenzene in certain countries, i.e., Germany and Poland for the young age groups (10 and 3 years respectively).

49. In the fennel fruit infusions consumers scenario, the highest average exposures were in other children (16.1 µg/kg bw), followed by toddlers (5.86 µg/kg bw) and infants (4.75 µg/kg bw). At P95 the highest exposure was reported for toddlers (17.4 µg/kg bw), followed by infants (17.3 µg/kg bw) and other children (14.4 µg/kg bw). A summary of these exposures is provided in Table 10 of the draft EFSA opinion.

50. For the fennel fruit consumers scenario EFSA draws attention to Figures 6 and 7 of the draft opinion which illustrate how consumption of fennel fruit infusions impacts exposure to *p*-allylalkoxybenzenes. These figures showed that in infants fennel fruit infusions may contribute to >75 % of the total average exposure to *p*-allylalkoxybenzenes. Furthermore, in toddlers and other children, infusions may contribute to >50 % of the total average exposure to *p*-allylalkoxybenzenes. In general, as age increase the relative contribution of fennel fruit infusions to average *p*-allylalkoxybenzene exposure decreases with an exception for the elderly where contribution may also exceed 50 %. A summary of the calculated MoEs for the fennel infusion consumer scenario is provided in Table 10 of the draft EFSA opinion. Appendix A.2 of the draft EFSA opinion provides lists of the MoEs for total *p*-allylalkoxybenzenes exposure in the fennel fruit infusion consumer scenario for each EU Member State. Please note, there are two tables named “Table 10” in the draft opinion in Section 3.7.2.2.