

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)

EFSA Draft Opinion

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

9. The risk assessment by the EFSA Panel on Nutrition, Novel Foods and Food Allergens (NDA) considered:

- “Is there a link between the consumption of preparations from the fruits of sweet and bitter fennel and harmful effects on health?”
- “What is the maximum level of total chronic daily intake (i.e. daily intake over a substantial part of the lifespan) of preparations from the fruits of sweet and bitter fennel, which is unlikely to pose a risk of adverse health effects to humans?”

10. These overarching questions were split into sub-questions (sQs) alongside methods to address each sQ (please see Table 1 of the draft opinion).

11. For detail on data collection and methodologies please see Sections 2.1 and 2.2, respectively. Please note that EFSA decided to calculate the margin of exposure (MoE) for total *p*-allylalkoxybenzenes and then establish the extent of the contribution of fennel fruit preparations to the total *p*-allylalkoxybenzenes exposure. This approach was taken because *p*-allylalkoxybenzenes are also present in other foods in the diet, not only fennel fruit preparations, and therefore exposure to *p*-allylalkoxybenzenes was unavoidable.

12. EFSA carried out two dietary exposure scenarios, one was a general chronic dietary exposure scenario while the other scenario considered 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 (for detail see Section 2.2.2).