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)

Introduction and Background

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

Introduction

1. EFSA published a public consultation on a draft Opinion on the safety of preparations from the fruits of sweet and bitter fennel on 16th of July 2025 (see Annex A for link). The COT are being asked to review the draft opinion and provide any comments they may have; the Secretariat will then submit the Committee's comments to EFSA.

2. A document has been provided in the Members Area Teams folder, for Members to add comments before or after the COT Meeting but can also send any additional comments directly to the Secretariat. The closing date for the public consultation is the 17th of September 2025. Please provide any comments latest by **Friday the 12th of September** giving the relevant line and section number where possible.

3. The following paper provides a brief overview of the draft EFSA Opinion.

Background

4. Following a requested by the European Commission (EC) EFSA provided an assessment on the intake of preparations from the fruits of *Foeniculum vulgare* Miller subsp. *vulgare* var. *vulgare* (bitter fennel) and *Foeniculum vulgare* Miller subsp. *vulgare* var. *dulce* (Miller) Thellung (sweet fennel). The EC request followed safety concerns raised by the German Federal Institute for Risk Assessment (BfR) in relation to possible adverse effects associated with the consumption of fennel fruit preparations by infants and young children due to the presence of estragole, a known genotoxic carcinogen.

5. Estragole belongs to the group of alkoxy-substituted allylbenzenes (*p*-allylalkoxybenzenes), and while estragole and other *p*-allylalkoxybenzenes are present in a variety of foods of the diet, estragole is the only member of this group present in fennel fruits and preparations thereof. *p*-Allylalkoxybenzenes all share similar structures, fates in the body and modes of action where their sulfooxy metabolites can lead to deoxyribonucleic acid (DNA) adduct formation (Smith et al., 2002; Hartwig et al., 2020; Eisenreich et al., 2021). Two *p*-allylalkoxybenzenes, methyleugenol and safrole, have also been classified as genotoxic carcinogens like estragole (Alajlouni et al., 2016; Götz et al., 2022). Furthermore, though no more *p*-allylalkoxybenzenes have been classified as genotoxic carcinogens most members of this group have been reported to lead to

DNA adduct formation (EFSA., 2022a). Two *in vivo* studies (Phillips et al., 1984; Randerath et al., 1984) suggested the following order of potencies for six *p*-allylalkoxybenzenes: methyleugenol > safrole > estragole > myristicin > elemicin > dillapiole. Estragole was demonstrated to be the most potent in an *in vitro* study (Zhou et al., 2007).

6. EFSA has not previously evaluated the safety of fennel fruit preparations, however, they have performed an assessment on the safety and efficacy of a feed additive consisting of an extract of olibanum from *Boswellia serrata* Roxb. ex Colebr. for use in dogs and horses which contains both estragole and methyleugenol (EFSA, 2022b). EFSA concluded that the additive is considered safe for consumers when used at the proposed conditions of use in horses. Furthermore, when individuals handle the additive unprotected, exposure to estragole and methyleugenol could not be excluded, therefore, to reduce the risk EFSA recommended that measures should be taken to minimise exposure.

7. The European Medicines Agency (EMA) Committee on Herbal Medicinal Products (HMPC) published a statement on the safety of human consumption of herbal medicinal products containing estragole (EMA HMPC, 2023) and recommended that exposure to estragole from medicinal products should be kept as low as practically achievable. An acceptable daily intake (ADI) could not be set but a guidance value of 0.05 mg estragole per day for adults and adolescents and 1 µg estragole per kg bw per day for children was suggested. The EMA did not recommend the use of fennel fruit infusions in children up to the age of 4 years or the use of fennel fruit preparations in pregnant or lactating women due to limited data on the extent of potential adverse effects in these sub-populations (EMA HMPC, 2024b, c).

8. In the draft opinion EFSA highlighted “Regulation (EC) No 1334/2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods prohibits the addition of estragole to foods and sets maximum levels of certain substances, naturally present in flavourings and food ingredients with flavouring properties, in compound foods. Estragole originating from food ingredients with flavouring properties may be present in dairy products, processed fruits and vegetables, nuts and seeds and fish products at a maximum concentration of 50 mg/kg and in non-alcoholic beverages at a maximum concentration of 10 mg/kg. These maximum levels do not apply where a compound food contains no added flavourings and the only food ingredients with flavouring properties which have been added are fresh, dried or frozen herbs and spices.”