



2026/334

17.2.2026

COMMISSION IMPLEMENTING DECISION (EU) 2026/334

of 13 February 2026

amending Decision 2008/911/EC establishing a list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products with regards to *Foeniculum vulgare*

(notified under document C(2026) 808)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use ⁽¹⁾, and in particular Article 16f thereof,

Whereas:

- (1) In 2007, the European Medicines Agency established in its opinions that *Foeniculum vulgare* Miller subsp. *vulgare* var. *vulgare*, fructus and *Foeniculum vulgare* Miller subsp. *vulgare* var. *dulce* (Miller) Thellung, fructus complied with the requirements set out in Directive 2001/83/EC as herbal substances, herbal preparations or combinations thereof within the meaning of that Directive and were therefore included in the list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products established by Commission Decision 2008/911/EC ⁽²⁾.
- (2) The Committee on Herbal Medicinal Products of the European Medicines Agency has reviewed the list entries *Foeniculum vulgare* Miller subsp. *vulgare* var. *vulgare*, fructus and *Foeniculum vulgare* Miller subsp. *vulgare* var. *dulce* (Miller) Thellung, fructus and adopted two respective opinions to change those entries. Based on those opinions, it is necessary to amend the scientific and common name of those herbal substances in EU official languages, the description of herbal preparations, the reference to the European Pharmacopoeia monograph, the numbering of the indications, the type of tradition, the specified posology, the duration of use, pharmaceutical particulars and the information on the safe use, including contraindications, special warnings and precautions for use with respect to fertility, pregnancy and lactation.
- (3) Decision 2008/911/EC should therefore be amended accordingly.
- (4) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use,

HAS ADOPTED THIS DECISION:

Article 1

Annex II to Decision 2008/911/EC is amended in accordance with the Annex to this Decision.

⁽¹⁾ OJ L 311, 28.11.2001, p. 67, ELI: <http://data.europa.eu/eli/dir/2001/83/oj>.

⁽²⁾ Commission Decision 2008/911/EC of 21 November 2008 establishing of a list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products (OJ L 328, 6.12.2008, p. 42, ELI: <http://data.europa.eu/eli/dec/2008/911/oj>).

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 13 February 2026.

For the Commission
Olivér VÁRHELYI
Member of the Commission

ANNEX

In Annex II, the Community list entry on *Foeniculum vulgare* Miller subsp. *vulgare* var. *vulgare*, fructus and the Community list entry on *Foeniculum vulgare* Miller subsp. *vulgare* var. *dulce* (Miller) Thellung, fructus are replaced by the following:

‘A. UNION LIST ENTRY ON FOENICULUM VULGARE MILLER SUBSP. VULGARE VAR. VULGARE, FRUCTUS

Scientific name of the plant

Foeniculum vulgare Miller subsp. *vulgare* var. *vulgare*

Botanical family

Apiaceae

Herbal substance

Bitter fennel, fruit

Common name of herbal substance in all EU official languages

BG (bulgarski): Горчиво резене, плод	LT (lietuvių kalba): Kartieji pankolių, vaisiai
CS (čeština): Plod fenyklu obecného pravého	LV (latviešu valoda): Rūgtā fenheļa, augļi
DA (dansk): Fennikel bitter	MT (malti): Bużbież morr, frotha
DE (Deutsch): Bitterer Fenchel	NL (nederlands): Bittere venkel, vrucht
EL (elliniká): Πικρού μάραθου καρπός	PL (polski): Koper włoski odmiany gorzkiej, owoc
EN (English): Bitter Fennel	PT (português): Funcho-amargo, fruto
ES (español): Hinojo amargo, fruto	RO (română): Fenicul amar, fruct
ET (eesti keel): Mõru apteegitill, vili	SK (slovenčina): Plod fenikla horkého
FI (suomi): Karvasfenkoli, hedelmä	SL (slovenščina): Plod grenkega navadnega komarčka
FR (français): Fenouil amer, fruit	SV (svenska): Bitterfänkål, frö
HR (hrvatski): Komorač gorki, plod	IS (íslenska): Bitur fennel aldin
HU (magyar): Keserű édeskömény, termés	NO (norsk): Bitter fennikel
IT (italiano): Finocchio amaro, frutto	

Herbal preparation(s)

Not applicable

European Pharmacopoeia monograph reference

Bitter fennel – *Foeniculi amari fructus* (04/2013:0824)

Indications

Indication (1)

Traditional herbal medicinal product for symptomatic treatment of mild, spasmodic gastro-intestinal complaints including bloating and flatulence.

Indication (2)

Traditional herbal medicinal product for symptomatic treatment of minor spasm associated with menstrual periods.

Indication (3)

Traditional herbal medicinal product used as an expectorant in cough associated with cold.

The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use.

Type of tradition

European

Specified strength

Please see "Specified posology"

Specified posology

Indications (1) and (3)

Adults and adolescents

Single dose

Herbal tea: 1,5 g of herbal substance in 250 ml of boiling water (steep for 15 minutes) as a herbal infusion, 3 times daily.

Recommended daily dose: 4,5 g

Children between 4 and 12 years of age

Single dose

Herbal tea: 1,0 g of herbal substance in 100 ml of boiling water (steep for 15 minutes) as a herbal infusion, 3 times daily.

Recommended daily dose: 3,0 g

For further information on the use in children between 4 and 12 years of age, see section "Special warnings and precautions for use".

The use is not recommended in children under 4 years of age (see section "Special warnings and precautions for use").

See section "Pharmaceutical particulars" for content of estragole.

Indication (2)*Adults and adolescents*

Single dose

Herbal tea: 1,5 g of herbal substance in 250 ml of boiling water (steep for 15 minutes) as a herbal infusion, 3 times daily.

Recommended daily dose: 4,5 g

The use in children under 12 years of age is not recommended (see section "Special warnings and precautions for use").

See section "Pharmaceutical particulars" for content of estragole.

Route of administration

Oral use

Duration of use or any restrictions on the duration of use

Indications (1), (2) and (3)

Adults and adolescents

Not to be taken for more than 2 weeks.

Indications (1) and (3)

Children between 4 and 12 years of age

For short-term use in mild transitory symptoms only (less than one week).

If the symptoms persist during the use of the medicinal product, a doctor or a qualified health-care practitioner should be consulted.

Any other information necessary for the safe use

Contraindications

Hypersensitivity to the active substance or to Apiaceae (Umbelliferae) family (aniseed, caraway, celery, coriander and dill) or to anethole.

Hypersensitivity to mugwort pollen, due to cross-reactivity with fennel.

Special warnings and precautions for use

Indications (1) and (3)

The use in children between 4 and 12 years of age is not recommended if the daily intake of estragole exceeds the guidance value of 1,0 µg/kg bw, unless justified by a risk assessment based on adequate safety data.

The use is not recommended in children under 4 years of age due to the lack of adequate data.

Indication (2)

The use in children under 12 years of age has not been established due to lack of adequate data.

If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.

Interactions with other medicinal products and other forms of interaction

None reported

Fertility, pregnancy, and lactation

Safety during pregnancy and lactation has not been established.

In the absence of sufficient data, the use during pregnancy and lactation is not recommended.

There is evidence that *trans*-anethole is excreted in human breast milk.

No fertility data available.

Effects on ability to drive and use machines

No studies on the effect on the ability to drive and use machines have been performed.

Undesirable effects

Allergic reactions to fennel, affecting the skin or the respiratory system, may occur. The frequency is not known.

If other adverse reactions not mentioned above occur, a doctor or a qualified health-care practitioner should be consulted.

Overdose

No case of overdose has been reported.

Pharmaceutical particulars

In the general population exposure to estragole should be kept as low as practically achievable.

In pregnant and breast-feeding women, the daily intake of estragole should be below 0,05 mg/person per day.

In children below 12 years of age, the daily intake of estragole should be below 1,0 µg/kg bw.

For further details see the “Public statement on the use of herbal medicinal products containing estragole”*.

Pharmacological effects or efficacy plausible on the basis of long-standing use and experience

Not applicable.

- * “Public statement on the use of herbal medicinal products containing estragole” of 12 May 2023 of the Committee on Herbal Medicinal Products, EMA/HMPC/137212/2005, Rev 1 Corr 1, available at: https://www.ema.europa.eu/en/documents/other/public-statement-use-herbal-medicinal-products-containing-estragole-revision-1_en.pdf.

B. UNION LIST ENTRY ON FOENICULUM VULGARE MILLER SUBSP. VULGARE VAR. DULCE (MILL.) BATT. & TRAB., FRUCTUS

Scientific name of the plant

Foeniculum vulgare Miller subsp. *vulgare* var. *dulce* (Mill.) Batt. & Trab.

Botanical family

Apiaceae

Herbal substance

Sweet fennel, fruit

Common name of herbal substance in all EU official languages

BG (bulgarski): Сладко резене, плод	LT (lietuvių kalba): Saldieji pankolių, vaisiai
CS (čeština): Plod fenyklu obecného sladkého	LV (latviešu valoda): Saldā fenheļa, augļi
DA (dansk): Fennikel sød	MT (malti): Bużbież ħelu, frotta
DE (Deutsch): Süßer Fenchel	NL (nederlands): Zoete venkel, vrucht
EL (elliniká): Γλυκού μάραθου καρπός	PL (polski): Koper włoski odmiany słodkiej, owoc
EN (English): Sweet fennel, fruit	PT (português): Funcho-doce, fruto
ES (español): Hinojo dulce, fruto	RO (română): Fenicul dulce, fruct
ET (eesti keel): Magus apteegitill, vili	SK (slovenčina): Plod fenikla sladkého
FI (suomi): Makeafenkoli, hedelmä	SL (slovenščina): Plod sladkega navadnega komarčka
FR (français): Fenouil doux, fruit	SV (svenska): Sötfänkål, frö
HR (hrvatski): Komorač slatki, plod	IS (íslenska): Sæt fennel aldin
HU (magyar): Édeskömény termés	NO (norsk): Söt fennikel
IT (italiano): Finocchio dolce, frutto	

Herbal preparation(s)

Not applicable

European Pharmacopoeia monograph reference

Sweet fennel – *Foeniculi dulcis fructus* (04/2011:0825))

Indications

Indication (1)

Traditional herbal medicinal product for symptomatic treatment of mild, spasmodic gastro-intestinal complaints including bloating and flatulence.

Indication (2)

Traditional herbal medicinal product for symptomatic treatment of minor spasm associated with menstrual periods.

Indication (3)

Traditional herbal medicinal product used as an expectorant in cough associated with cold.

The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use.

Type of tradition

European

Specified strength

Please see "Specified posology"

Specified posology

Indications (1) and (3)

Adults and adolescents

Single dose

Herbal tea: 1,5 g of herbal substance in 250 ml of boiling water (steep for 15 minutes) as a herbal infusion, 3 times daily.

Recommended daily dose: 4,5 g

Children between 4 and 12 years of age

Single dose

Herbal tea: 1,0 g of herbal substance in 100 ml of boiling water (steep for 15 minutes) as a herbal infusion, 3 times daily.

Recommended daily dose: 3,0 g

For further information on the use in children between 4 and 12 years of age, see section "Special warnings and precautions for use".

The use is not recommended in children under 4 years of age (see section "Special warnings and precautions for use").

See section "Pharmaceutical particulars" for content of estragole.

Indication (2)*Adults and adolescents*

Single dose

Herbal tea: 1,5 g of herbal substance in 250 ml of boiling water (steep for 15 minutes) as a herbal infusion, 3 times daily.

Recommended daily dose: 4,5 g

The use in children under 12 years of age is not recommended (see section "Special warnings and precautions for use").

See section "Pharmaceutical particulars" for content of estragole.

Route of administration

Oral use

Duration of use or any restrictions on the duration of use

Indications (1), (2) and (3)

Adults and adolescents

Not to be taken for more than 2 weeks.

Indications (1) and (3)

Children between 4 and 12 years of age

For short-term use in mild transitory symptoms only (less than one week).

If the symptoms persist during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.

Any other information necessary for the safe use

Contraindications

Hypersensitivity to the active substance or to Apiaceae (Umbelliferae) family (aniseed, caraway, celery, coriander and dill) or to anethole.

Hypersensitivity to mugwort pollen, due to cross-reactivity with fennel.

Special warnings and precautions for use

Indications (1) and (3)

The use in children between 4 and 12 years of age is not recommended if the daily intake of estragole exceeds the guidance value of 1,0 µg/kg bw, unless justified by a risk assessment based on adequate safety data.

The use is not recommended in children under 4 years of age due to the lack of adequate data.

Indication (2)

The use in children under 12 years of age has not been established due to lack of adequate data.

If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.

Interactions with other medicinal products and other forms of interaction

None reported

Fertility, pregnancy and lactation

Safety during pregnancy and lactation has not been established.

In the absence of sufficient data, the use during pregnancy and lactation is not recommended.

There is evidence that *trans*-anethole is excreted in human breast milk.

No fertility data available.

Effects on ability to drive and use machines

No studies on the effect on the ability to drive and use machines have been performed.

Undesirable effects

Allergic reactions to fennel, affecting the skin or the respiratory system, may occur. The frequency is not known.

If other adverse reactions not mentioned above occur, a doctor or a qualified health-care practitioner should be consulted.

Overdose

No case of overdose has been reported.

Pharmaceutical particulars

In the general population exposure to estragole should be kept as low as practically achievable.

In pregnant and breast-feeding women, the daily intake of estragole should be below 0,05 mg/person per day.

In children below 12 years of age, the daily intake of estragole should be below 1,0 µg/kg bw.

For further details see the “Public statement on the use of herbal medicinal products containing estragole”^{*}.

Pharmacological effects or efficacy plausible on the basis of long-standing use and experience

Not applicable.

- ^{*} “Public statement on the use of herbal medicinal products containing estragole” of 12 May 2023 of the Committee on Herbal Medicinal Products, (HMPC) EMA/HMPC/137212/2005, Rev 1 Corr 1, available at: https://www.ema.europa.eu/en/documents/other/public-statement-use-herbal-medicinal-products-containing-estragole-revision-1_en.pdf.
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