Botanical flavourings - ad hoc meeting
Specifications

Agenda

1. How specifications are set in authorizing regulations
    1.1. Established approach for essential oils – the example of juniper oil
    1.2. Other extracts – challenges with juniper tincture

2. Proposed standard approach for specifications (for extracts other than essential oils)

1.1. Established approach for essential oils

SIn reply Juniper oil (02/02/2021)

Additive composition	Essential oil obtained by steam distillation of the fresh, dried or fermented berries from *Juniperus communis* L.
Characterization of the active substance	— Pin-2(3)-ene: 25-45% — 4(10)-Thujene: 4-20% — Pin-2(10)-ene: 1-12% — Myrcene: 3-22% CAS number 8002-68-4

EFSA Journal 2023;21(4):7977

3. Assessment

3.1. Origin and extraction

The essential oil is extracted from ripe fresh, dried or fermented berries (seed cones) by steam distillation. Released volatile compounds are collected and condensed and then separated from the aqueous fraction by decantation.

3.2. Juniper oil

3.2.1. Characterisation of the juniper oil

Table 2: Main constituents of the essential oil from the berries of *Juniperus communis* L. as defined by specifications: batch to batch variation based on the analysis of five batches. The

Constituent EU register name	CAS No	FLAVIS No	% GC area		
			Specification	Mean	Range[a]
α-Pinene (pin-2(3)-ene)	80-56-8	01.004	25–45	41.0	39.6–44.2
Myrcene	125-35-3	01.008	3–22	10.6	4.9–12.9
Sabinene (4(10)-thujene)	3387-41-5	01.059	4–20	8.2	7.5–9.7
β-Pinene (pin-2(10)-ene)	127-91-3	01.003	1–12	5.0	4.3–7.3

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1.1. Established approach for essential oils

Regulation (EU) 2024/2414 – Juniper oil

2b249-eo	Juniper essential oil	*Additive composition* Essential oil from the berries of *Juniperus communis* L.
		Characterisation of the active substance Juniper essential oil Essential oil as defined by the Council of Europe (1) obtained from the berries of *Juniperus communis* L. by steam distillation and further condensation of volatile constituents and separation from the aqueous phase by decantation.
		Specifications ►**C1** α-Pinene (pin-2(3)-ene): 25-45 % β-Pinene (pin-2(10)-ene): 1-12 % Sabinene (4(10)-thujene): 4-20 % Myrcene: maximum 3-22 % ◄

Specifications in the authorizing regulation
= specifications reported in the EFSA opinion
= specifications proposed by the applicant

1.2. Other extracts – challenges with juniper tincture

SIn reply Juniper tincture (31/01/2023)

Additive composition	Juniper tincture prepared from of *Juniperus communis* L. Extracted with ethanol/water (65:35) from dried ripe cone berries of *Juniperus communis* L
Characterization of the active substance	Juniper tincture from dried ripe cone berries of *Juniperus communis* L. – Tannins (expressed as pyrogallol): 20 – 200 mg/kg – Phytochemical marker: Tannins (expressed as pyrogallol)

EFSA Journal 2023;21(4):7977

3. Assessment

3.1. Origin and extraction

The tincture is obtained by maceration of whole dried cone berries in a water/ethanol mixture (35/65, v/v) for a period of 2 h at 35°C under stirring. The ratio of dry raw material to solvent is

3.3. Juniper tincture

3.3.1. Characterisation of juniper tincture

The tincture under assessment has a density of 895–902 kg/m^3 (898 kg/m^3 on average, five batches). It is a water/ethanol (35/65, v/v) solution, specified to contain 20–200 mg/kg tannins (corresponding to 0.002–0.02%, w/w), which are selected as the phytochemical marker.[29]

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1.2. Other extracts – challenges with juniper tincture

Regulation (EU) 2024/2414 – Juniper tincture

2b249-t	Juniper tincture	*Additive composition* Tincture from the berries of *Juniperus communis* L. Liquid form *Characterisation of the active substance* Juniper tincture Tincture as defined by the Council of Europe (1)obtained from the berries of *Juniperus communis* L. by extraction with a water/ethanol solvent mixture, pressing and filtration. CoE number: 249 *Specifications* Dry matter: maximum 1,5 % Tannins (as pyrogallol): maximum 0,02 % α-Pinene: maximum 0,0064 %

Specifications in the authorizing regulation ≠ specifications reported in the EFSA opinion (inclusion of alpha pinene at max. measured concentrations)

1.2. Other extracts – challenges with juniper tincture

Regulation (EU) 2024/2414 – Juniper tincture

α-Pinene: maximum 0,0064 %

Inclusion of **alpha Pinene** at max. measured concentration not understood by the applicant because:

- Inconsistent with the treatment of other parameters, such as dry matter and tannins
- No safety concerns
  - juniper tincture at max. proposed level of 45 mg/kg feed

  ⇔ ca. 0.0029 mg alpha pinene/kg feed while safe level 5 mg/kg
- No EFSA recommendations towards alpha-pinene in the opinion
- The applicant did not know that alpha pinene would be included in the specifications while working on the dossier. An upper range of 0.01% was proposed later but refused by the EC.

2. Proposed standard approach for specifications

Proposed approach for specifications:

- EC draft based on specifications reported in EFSA opinion (paragraphs “Characterization of ADDITIVE” and “Recommendations”)

- If an additional constituent should be included (e.g. to better define the additive):
  - Should accommodate natural variability (= cannot be based on analysis of 5 batches) (applicant to be consulted)
  - Upper range for this constituent to be considered in the safety assessment