

Characterisation of botanical preparations for risk – benefit assessment

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Identity of the source material

- Different species = different chemical composition

  (e.g. *Cannabis sativa* vs. *Cannabis indica*)

- Different varieties / cultivars (of same species) = different chemical content

  (e.g. *Ocimum tenuiflorum*: up to 86% of methyleugenol in the essential oil).

Nature of the source material

- Different parts of a same plant = different phytochemical composition

  (e.g. fruits of *Solanum lycopersicum* are edible while leaves are toxic (alkaloids))

Cultivation place, growth and harvesting conditions

- Thujone content of *Salvia officinalis* is very different whether cultivated in hot or cold countries

Type of preparation / manufacturing process

Variety of phytochemical compounds with differences in hydrophilic or lipophilic character

Infusion : hydrosoluble compounds

Hydroalcoholic extracts: less polar compounds can be extracted to a certain extent

Supercritical CO2 extraction: lipid and hydrophilic fractions can be separated

Steam distillation: volatile compounds

Other solvent extractions: specific compounds can be extracted

Type of preparation / manufacturing process

Tea sinensis

Full polyphenol oxidation → thearubigins → black tea

Limited oxidation → oolong tea

No oxidation → green tea

Water extract:

< 2 min: alkaloids (caffein) solubilised, followed by tannins and flavonoids

Tea has first an excitant effect, which then becomes relaxing

"Tea extract" is therefore not sufficient to explain the chemical contents and the effect of a preparation

Type of data needed by risk assessors

- NDA technical guidance for the preparation and presentation for authorisation of a health claim:

  http://www.efsa.europa.eu/en/efsajournal/doc/530.pdf

- SC guidance for the safety assessment of botanicals and botanical preparations intended for use as ingredients in food supplements:

  http://www.efsa.europa.eu/en/efsajournal/doc/1249.pdf

- FEEDAP guidance for the preparation of dossiers for sensory additives:

  http://www.efsa.europa.eu/en/efsajournal/doc/1352.pdf

- EC guidance on submissions for safety evaluation of sources of nutrients or other ingredients proposed for use in the manufacture of foods:

  http://ec.europa.eu/food/fs/sc/scf/out100_en.pdf

Technical data required to assess safety

- Identity and nature of the source material

Scientific (Latin) name: *full systematic species name incl. botanical family, genus, species, variety, subspecies, author's name, and chemotype, if applicable*

Synonyms: *botanical name(s) that may be used interchangeably with the preferred scientific name*

Common names: *vernacular name(s)*

Part used: *e.g. root, leaf, seed …*

Geographical origin: *continent, country, region*

Growth and harvesting conditions: *wild or cultivated, cultivation practices, time of harvest in relation to both season and stage of the plant growth.*

Technical data required to assess safety

- Manufacturing process
  - information on the method(s) of manufacture
  - information on substances entering the manufacturing process
  - standardization criteria

- Chemical composition
  - classify compounds according to their chemical structure.
  - provide levels at which the constituents are present in the respective part of the botanical or botanical preparation
  - concentration of constituents to characterise the quality, chemical fingerprint, production process and/or biological activity of the preparation.
  - concentrations of constituents of concern due to their chemical, physiological or toxicological properties.

Technical data required to assess safety

- Specifications

Limits for or absence of specific undesirable / toxic substances should be specified.

Modelled on recent European or other internationally accepted specifications.

Where the proposed specifications differ from internationally recognised specifications, the latter specifications should be set out alongside the proposed new specifications, and any differences pointed out.

- Stability of the botanical (preparation) used as ingredient in food supplements

Should be demonstrated over the shelf-life time.

- Proposed uses and use levels (exposure assessment)
  - Common foods
  - Food supplements
  - Medicinal products

Information on the duration of the proposed uses

Difficulties encountered

- Extremely difficult to find trustable information:
  - on the amount of substances
    - Depends on different factors like geographical origin, stress factors, hybridisation, (mostly unknown) genetic factors, …
  - in which herbal part(s?) they are present
    - E.g. pyrrolizidine alkaloids found in root. Does this mean no alkaloids in leaves?

New analytical methods and tools can help risk assessors to:

- identify and characterise plants' constituents of concern
- identify and characterise potential adulterations and contaminants

Thank you for your kind attention

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