Botanically defined flavourings: an overview

EFSA - Info Session on Applications - FEED

Technical Meeting with Stakeholders on Feed Additives Applications

Barcelona - 6 May 2015

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Introduction

- About the use of Botanical Feed Flavourings
- Market overview and trade channels

Botanical Feed Flavourings

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- How are botanical flavourings used in feed?

Current Industry Practice

- Botanicals are chemical entities, including a complex profile of several single compounds and providing a natural well balanced flavour.
- Botanicals are used as ingredients of flavouring mixtures, but also as single flavouring compound.
- The number, type and concentration of botanical flavourings included in a formula depend mainly on the desired qualitative and quantitative sensory effect in the feedingstuff.
- The dose range of botanical flavourings is comparable to the use of chemically defined flavourings

Overall range between 0.01 to 125 mg/kg feed

Botanical Feed Flavourings

- Which types of botanical flavourings are used?

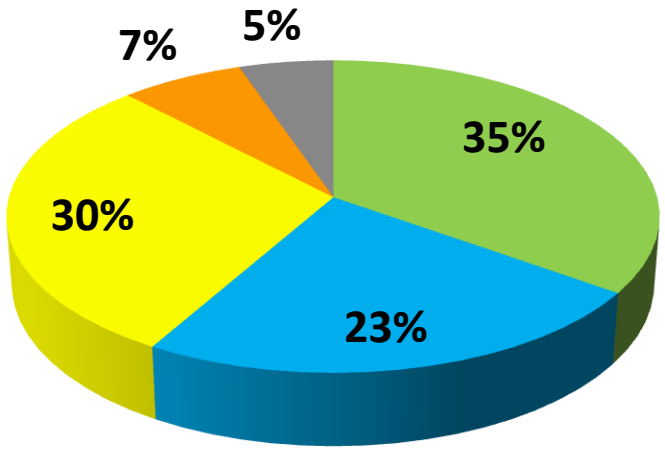
Type of Botanical

- EO ➡ Essential oil
- EX ➡ Extract
- TI ➡ Tincture
- O ➡ Oleoresin
- R ➡ Remains: absolute, distillate, concentrate and terpenes

Distribution of FFAC

Botanically Defined Flavourings

Total BDF : 246



Based on the specifications of the International Organization of Standardization

Botanical Feed Flavourings

- From plant to feeding trough

FFAC members

Plant	Botanical	Feed Flavouring	Compound Feed	Animal Feeding
				
• Farming / wild harvesting • Basic processing of plants on farm (e.g. distillation)	• Analytics • Identity • Development of specifications • Quality control • Standardisation • Fractioning	• Blending of flavouring compounds • Coating • Spray on carrier material	• Mixing of feed materials with additives • Processing (e.g. pelletizing)	• Feeding compound feed

Market & Trade Channels

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Plants

Most of the plants used are grown in markets outside the EU. Produced by small farmers beside their captive food production to generate cash.

Botanical composition vary depending on its origin

Harvest & Basic processing

Basic processing of essential oils on farm direct after harvesting. Small farms sell to cooperation or trading companies.

Starting point of analytical quality control

Composition, %	Rosemary oil spanish type	moroccan type
a-pinene	18 - 26	9 - 14
camphene	8 - 12	2.5 - 6.0
b-pinene	2.0 - 6.0	4.0 - 9.0
b-myrcene	1.5 - 5.0	1.0 - 2.0
limonene	2.5 - 5.0	1.5 - 4.0
cineole	16 - 25	38 - 55
p-cymene	1.0 - 2.2	0.8 - 2.5
camphor	13 - 21	5.0 - 15
bornyl acetate	0.5 - 2.5	0.1 - 1.5
a-terpineol	1.0 - 3.5	1.0 - 2.6
borneol	2.0 - 4.5	1.5 - 5.0
verbenone	0.7 - 2.5	< 0.4

Market & Trade Channels

- Trade channel of botanicals

Cooperative/ trade, export

- Collecting small batches
- Exporters offer combined batches for trading and manufacturing

EU Manufacturer of Botanicals

- Purchase specifications (lead substances, impurities, substances of concern)
- Further processing
- Distribution to different markets

Food

Pharma

Cosmetics

Feed

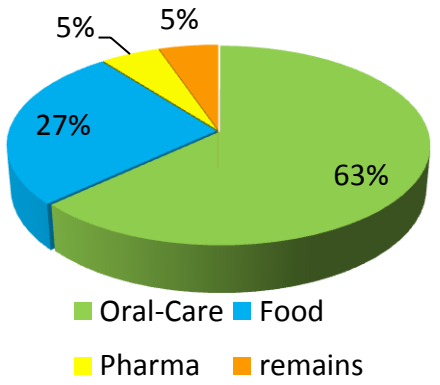
others

Market & Trade Channels

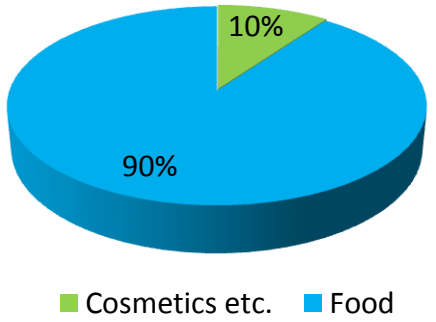
- Distribution of Botanicals in different markets

  - Manufacturer of essential oils and other botanical extracts produce botanicals for different markets.
  - The market distribution of essential oils and other botanical extracts differs between the botanicals.
  - The predominant user of botanicals is the food industry. Less the 10% of the overall botanical production is used in the feed industry.

Mint oil: 12,500 to



Star anise oil: 4,000 to



Impact on business

- Botanical extracts are manufactured by companies which distribute these botanicals to different industries, including food and feed flavouring industry.
- The industry needs a coherent safety assessment for botanicals in the whole food chain, including food and feed use.
- FFAC is willing to generate new data for the specific use as feed flavouring which are required for the safety evaluation of botanicals

BOTA dossiers

- Characterisation, analytics, safety and efficacy

Botanical Group Dossiers

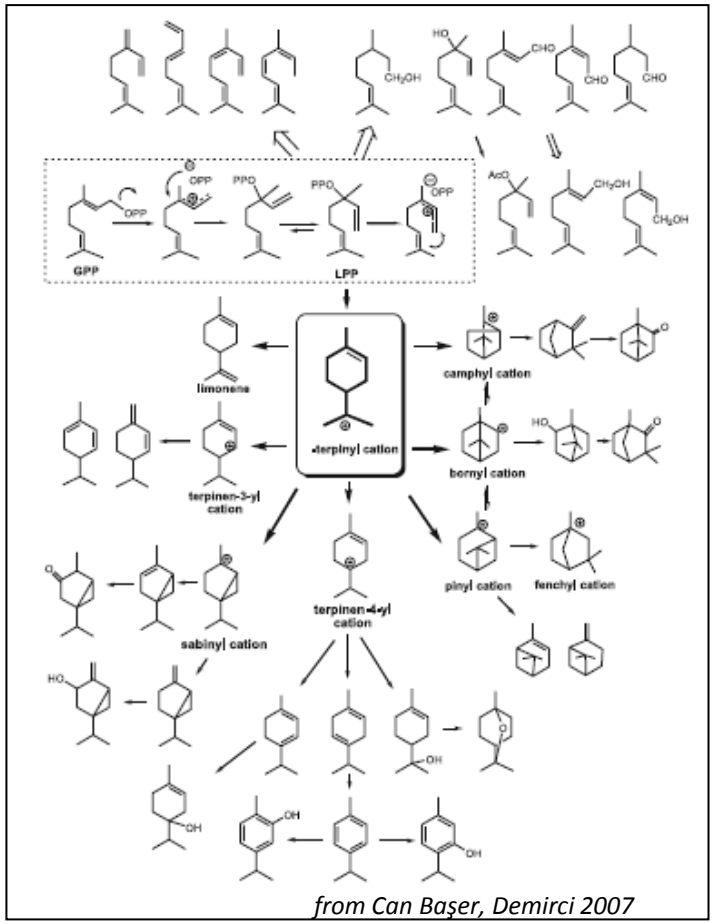
- Twenty group dossiers based on taxonomy (mainly plant orders plus one for pets)
- 268 additives
- All sections followed pertinent guidance by 429/2008 and FEEDAP
- Focus on Article 10 (2): collection of available data
- Monographs for each plant species (based on literature review)

Dossier	Taxo-nomy	Plants	Addi-tives
BDG 1	Lamiales	thyme, peppermint, rosemary	40
BDG 2	Apiales	fennel, caraway, anise	29
BDG 3	Aspara-gales	onion, garlic, vanilla	11
BDG 4	Asterales	chamomila, artichoke, stevia	26
BDG 5	Fabales	licorice, quillaia, fenugreek	16

Botanical Group Dossiers

- Section II: Characterisation

  - Comprehensive database on characterisation and composition
  - Marker substances, restricted substances (i.e. substances of concern), other constituents (as available)
  - Specifications in line with the approach for chemically defined flavourings; focus on markers and identification



from Can Başer, Demirci 2007

Botanical Group Dossiers

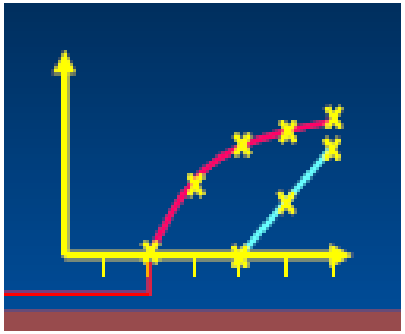
- Section II: Analytics

  - Dossier: analytical methods for markers
  - Different status re method validation
  - Agreement with EURL to revise Section 2.6.1 post-submission for all twenty dossiers
  - Additional work for all markers and extracts (2011/12):
    - Analytical method validated and verified
    - Applicability to other matrices
    - Applicability solid and liquid premixtures

Botanical Group Dossiers

- Section III: Safety

  - Focus on markers and substances of concern
  - Calculate maximum acceptable feed concentration (MAFC) for markers and substances of concern
  - Lowest MAFC will determine MAFC for extract
  - Metabolism of markers and other constituents by reference to chemically defined flavourings



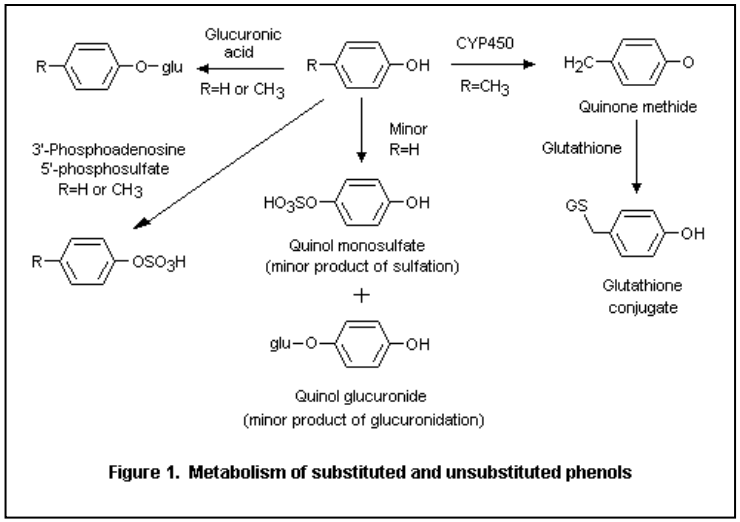


Figure 1. Metabolism of substituted and unsubstituted phenols

Botanical Group Dossiers

- Section IV: Efficacy

  - *"For flavourings already authorised for use in food, where the functions of the additive applied for feed use and described for food use are similar, no further demonstration of efficacy is generally necessary."* (EFSA 2009)

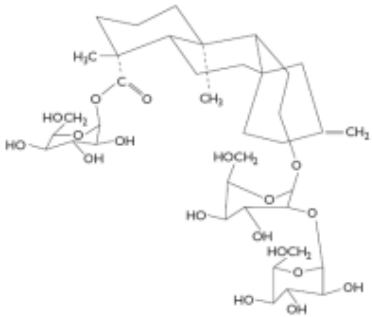
  - For non-food flavourings further evidence of their taste/smell is provided

Evaluation - a joint project

- Completing the characterisation
- Specific safety issues
- Proposal for prioritization

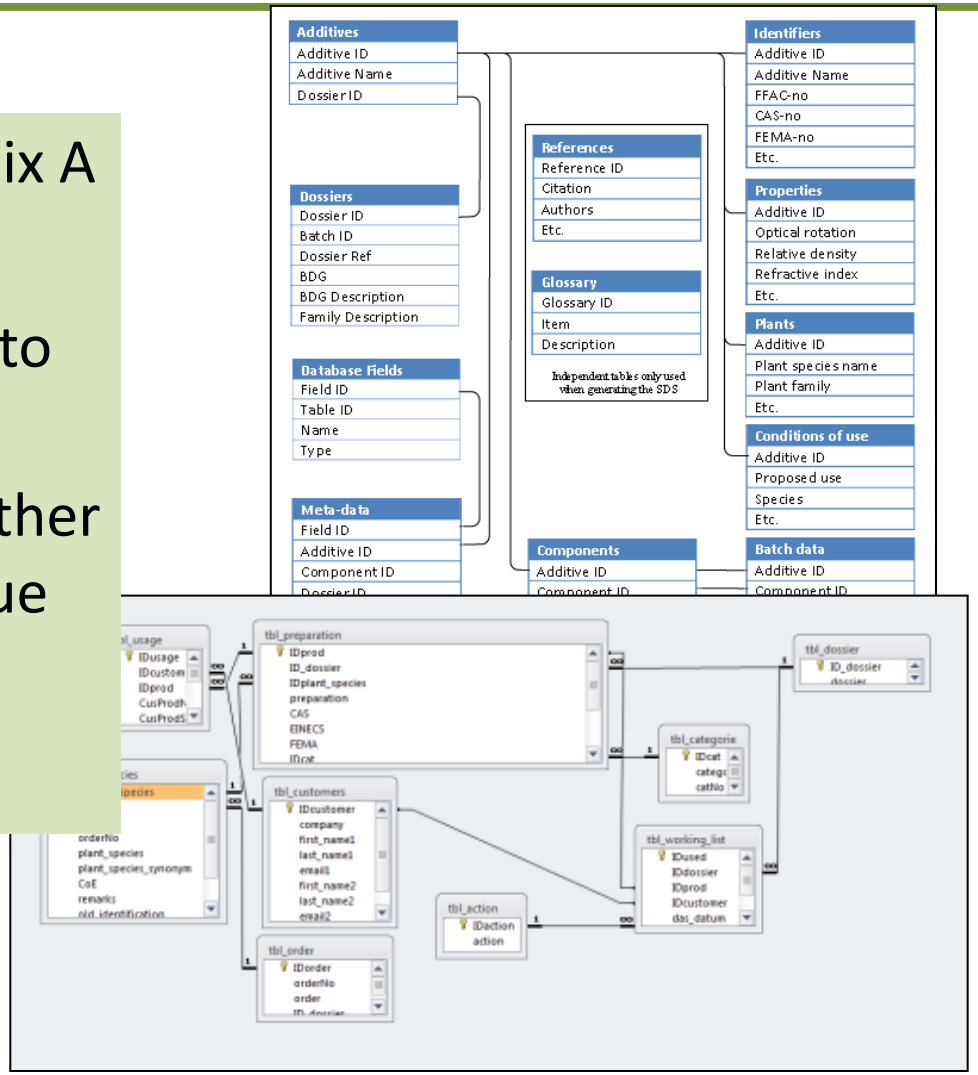
Completing the characterization

- FFAC pilot project initiated in 2014
- Develop working arrangements for multiple companies (24) work
- Characterize the additive, raw material, and its manufacturing
- Provide full qualitative/quantitative description for five batches for each additive
- Provide analytical certificates from each company (compliance with specifications)



Completing the characterization

- Hertfordshire report – Appendix A
- “Data requirements checklist”
- Hazard based approach (need to know):
- Constituents, impurities and other parameters: only if required due to raw material or processing steps



Specific safety issues

FEEDAP: 109th Plenary Meeting (27-29 January 2015):

"A discussion took place regarding the presence of substances with genotoxic-carcinogenic properties, like estragole and methyl eugenol, in feed additives. These substances are components of essential oils of botanical origin, like star anise oil and clove oil. The Panel stated that the intentional addition of such substances to the food chain via feed additives is not acceptable. This applies independently from the origin of the substances (chemical synthesis or botanical origin)."

Plants of concern ?

- Impact of EFSA statement on botanical flavourings

~ 30% of botanicals are affected, some examples

Dossier	Plant	Additive	Substance	%
BDG01	Ocimum basilicum	Basil oil	Estragole Methyl eugenol	10 – 90 0 – 2.5
BDG02	Pimpinella anisum	Anise oil	Estragole	0 – 10
BDG02	Illicium verum	Anise star tincture	Estragole	0 – 6
BDG02	Foeniculum vulgare	Fennel tincture	Estragole	0 – 7
BDG04	Artemisia dracunculus	Tarragon oil	Estragole	70 – 90
BDG06	Laurus nobilis	Laurel leaves extract/oleoresin	Methyl eugenol	0 – 3
BDG06	Cananga odorata	Ylang-ylang oil	Methyl eugenol	0 – 2
BDG07	Pimenta racemosa	Bay oil	Methyl eugenol	1 – 3
BDG07	Pimenta dioica	Allspice oil	Methyl eugenol	2 – 10

Acceptable levels possible

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- Exposure of methyleugenol

Maximum accepted feed concentration (MAFC)
Clove oil ≤ 90 mg/kg feed (depending on eugenol level)
Methyleugenol ≤ 0.2 mg/kg feed

Regulation (EC) Nº 1334/2008, Annex III Part B

Substance	Restriction in food	Max. level mg/kg
Methyleugenol	Dairy products	20
	Meat products	15
	Fish products	10
	Soups and sauces	60
	Ready-to-eat savouries	20
	Non-alcoholic beverages	1

EC project 245119: PlantLIBRA

Substance	$BMDL_{10}$ mg/kg BW/day	Fold difference [1]	Corrected $BMDL_{10}$ mg/kg BW/day	Estimated intake [2] mg/kg BW/day	MOE
Methyleugenol	15.3 – 34.0	41	627 - 1394	0.017	40,000 – 80,000

[1] toxicity rats vs. human
[2] estimated from spices, food and essential oils

Substances of concern

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- Questions to discuss
  - "Substances of concern" occurring in botanical flavourings enter the feed chain in lower dosages if compared to food
  - Considerations of the PlantLIBRA project: toxicity of botanicals is not the arithmetical sum of the toxicity of its ingredients
  - Target animal safety
    - Short life time of food producing animals
    - Metabolic pathways at low dosages
  - Consumer safety
    - exposure calculation should consider metabolism by animals
    - Crucial parameter for safety evaluation should be the presence of residues in animal tissues.

Proposal for prioritization

- Critical issues for evaluation of botanical feed flavourings
  - Plant material and processing
  - Characterisation of additives
  - Safety of markers and substances of specific concern

- Evaluate by application/dossier
  - Address horizontal issues specifically (e.g. safety of a constituent only one time – cross-reference between dossiers)
  - Start with less complex but representative pilot dossiers (2)

Conclusion

Conclusion

- The characterization effort and safety assessment for botanical extracts should be risk-based
- Presence of substances of concern in several botanical extracts calls for additional studies for confirming their safe use as feed additives.
- Active scientific collaboration between EFSA and FFAC shall enable efficient collection of recently generated data for elaboration of risk assessment within the whole food chain.