Key issues for the assessment of botanicals

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ORIGIN AND COMPOSITION

- Generic authorisations
- New users may enter market and existing users change their source of supply
- Batch to batch variation typically provided for feed additives is of less importance than evidence how representative is data from a single source

ORIGIN AND COMPOSITION

Specifications

- Existing specifications whether official or in-house are of limited value in setting the parameters for a safety assessment unless:
  - Used to limit the concentration of a (geno)toxic agent
  - Used to distinguish between chemotypes requiring separate safety assessments e.g Niaouli oil

COMPOSITION

- Safety assessment must consider all constituents
- Implications for many extracts where total identified constituents fall well below 100%
- Assessments made more difficult when use levels between 0.1 and 100 mg/kg feed are indicated.
- Use of dose ranges equivalent to those applied to the chemically-defined flavours?

ORIGIN AND COMPOSITION - QUESTIONS

- *What steps are taken to guarantee the biological origin of the material under assessment?*
- *Where analyses are provided for a number of batches, the do these derive from a single source/supplier or from multiple sources/suppliers?*
- *The WG needs to assess whether the compositional data provided is complete and representative of that available. For this purpose, the WG invites the applicant to provide a review of the available literature containing compositional data for each botanical preparation under application.*

PURITY AND USE LEVEL - QUESTIONS

- *The WG would like to know what steps are taken to ensure the absence of pesticide residues, mycotoxins other than aflatoxin, pyrrolizidine alkaloids, and where appropriate heavy metals (including mercury, cadmium, lead), arsenic, PAHs, dioxins and dioxin-like PCBs and microbial contamination.*
- *A clear statement on the proposed use level, and if applicable a maximum use level, for each preparation under application must be provided.*

COMPOSITION AND TARGET ANIMAL SAFETY

Assess individual constituents

- Use outcome for individual chemical flavours (if available)
- Consider any available toxicity data from which a NOAEL could be derived
- Default to the TTC in absence of data

Maximum safe level in feed determined by the lowest value obtained

IMPLICATIONS OF THE USE OF TTC

Cramer class	Max.safe feed use (mg/kg feed)	Max. intended use of extract (mg/kg feed)	
		5	25
I	1.0	20%	4%
II	0.3	6%	1.2%
III	0.05	1%	0.2%

Geranium essential oil

Ex *Pelargonium graveolens*

Compound	Conc. (%)	Cramer class	NOAEL	Max. Safe feed conc. (mg/kg feed)	
				Component	Oil
Citronellol	33.9	I	51	8.0	23.6
Geraniol	17.4	I	50	8.0	45.9
Citronellol formate	8.4	I	51	8.0	95.5
Isomenthone	6.9	II	-	0.3	4.4
Linalool	7.0	I	117	10	143.0
epi-γ-Eudesmol	4.7	III	-	0.05	1.1
Geranyl formate	3.4	I	50	8.0	234
Gerenyl acetate	2.3	I	50	8.0	356
Rose oxide	1.6	II	-	0.3	18.9

TARGET ANIMAL SAFETY

From the example of Geranium oil

- No toxicity data on the essential oil itself
- Conclusions on safety can only be drawn from the individual constituents
- None of the major constituents would allow a use level in feed of 100mg/kg or more
- Maximum use level likely to be set by minor constituents assessed by TTC

CONSUMER SAFETY

- Unlike the chemical flavours, very few botanical extracts have been assessed for consumer safety by EFSA
- Safety for consumers of each identified parent compound is given by the toxicity data used to establish target animal safety (NOAEL, TTC)
- Although specific data on mammalian metabolism is available, often there is none for fish or birds.
- Residues in milk and eggs?

USER SAFETY

- MSDS adequate, but for some extracts use in cosmetics and/or household products has generated relevant toxicity studies

Consequently:

- *A survey of the available literature including case reports relating to user/worker safety for each of the preparations under application is requested.*

ENVIRONMENTAL SAFETY

- Do extracts from plants of European origin (or widely distributed in Europe) require assessment?
- Would this apply to all compartments or only terrestrial?
- Use in all animal species includes aquaculture – is this a universal concern?
- Should an environmental safety assessment be built on results for the (major?) constituents?

KEY ISSUES NEEDING RESOLUTION

1) Availability of adequate data on the origin and composition of extracts under application
2) Need to rely on TTC for animal/human safety
3) Presence of genotoxic compounds
4) Scope of individual Opinions


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