

## **A database assisted process to determine safe use levels of complex botanical mixtures in animal nutrition**

The use of botanical preparations as feed additives in animal nutrition presents several challenges such as the variability of their composition, the lack of appropriate safety data for the preparations as such, the heterogeneity of possible chemical constituents.

EFSA proposed recently that the safety assessment of complex mixtures, if used as feed additives, may be performed by breaking them down to their individual chemical constituents and assess those based on the toxicological data available for them (EFSA 2009). Furthermore a maximum acceptable feed concentration for a target animal species may be derived from the no observed adverse effect level (NOAEL) obtained in a laboratory animal study for a chemical substance itself or a structurally related substance.

The safe use of botanical extracts in animal feed can be assisted by a newly developed database that contains all relevant publicly available information for their constituents. The objective of the assessment is to provide a quantitative use recommendation for an extract by determination of those constituent(s) that will limit the use due to the safety data and concentration in the extract. The processing of the data for a given extract and the information available in the database results in maximum acceptable feed concentrations (MAFC) that are expected to be safe for target animals.

The MAFC is based on the NOAEL obtained by appropriate toxicological studies, the body weight and daily feed intake of the target animal. Furthermore it depends on the proportion of the constituent in the specified product or an individual batch thereof.

All NOAEL values available in the database are selected taking into consideration the corresponding original studies, current EFSA and JECFA reports and relevant assessments by other authoritative bodies.

The database enables - apart from containing a comprehensive collection of chemical and toxicological data for frequently occurring constituents of botanical extracts - a straightforward working process from storing and assessing high volumes of data encountered in such projects up to presenting the calculations and results thereof. For a specified botanical extract or an individual batch the database provides users with practical information about the safe range of its use in animal nutrition.

**Keywords:** Botanical extracts, maximum acceptable feed concentration (MAFC), target animal safety, no observed adverse effect level (NOAEL), Safety Assessment Database

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