Botanical Safety Consortium

Stakeholder Council Webinar Series

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Chemical Safety of Phytomedicines – Perspectives for *in vitro* testing strategies?

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Abstract:

Plants used for the preparation of phytomedicines or food supplements may contain natural constituents causing a safety concern. Furthermore, contamination of such plants with various types of weeds may result in the occurrence of unwanted constituents.

Safety concerns typically arise from hazard considerations indicating genotoxic or carcinogenic properties of certain constituents in various test models. In addition, indications for system and/or organ toxicity may result form *in vitro* or animal experiments.

In modern safety assessment New and Alternative Methods (NAMs) are widely used in order to restrict animal experiments to a minimum. NAMs include all types of *in silico* and *in vitro* methods giving preference to those not requiring animal organs. Typically, such methods comprise *in vitro* genotoxicity testing, toxicity testing in tissue-specific cell culture, *in vitro* absorption and metabolism studies etc. Furthermore, *in vitro* searches for structural alerts including read-across of related structures are applied.

In addition to hazard identification, combined cell culture-based toxicokinetic and toxicodynamic testing strategies may allow modeling of effective target concentrations of a chemical and/or its metabolite(s) upon a defined (human) exposure.

Since natural plant constituents often occur as large numbers of derivatives (congeners), establishing relative toxic potency factors is required for a science-based risk assessment. For this purpose, NAMs provide an excellent tool even allowing structure-related predictions of potency. Examples will be demonstrated for the family of pyrrolizidine alkaloids, for phototoxic furanocoumarins and for the diverse group of alkenylbenzenes.