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Development of a Consensus Approach for Botanical Safety Evaluations.

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Continued interest in botanicals in a variety of consumer care products, coupled with a strong desire to eliminate animal testing, presents some unique challenges for this category of ingredients. There are various approaches for safety assessment of botanicals intended for use in food/dietary supplements, from reliance on capturing adverse events via post market surveillance, to tiered approaches building an assessment based on existing data and new data generated specifically to meet safety assessment needs. For example, critical data endpoints that are often lacking may include raw material characterisation, developmental and reproductive toxicity, genotoxicity/carcinogenicity testing, and/or ADME considerations (including herb-drug and herb-herb interactions).

To expand on the topic of botanical safety assessments, a scientific session entitled, “*Botanical safety evaluation in the era of alternatives*,” was held at the 53rd Congress of the European Societies of Toxicology (Eurotox) held in Bratislava, Slovakia (September 10-13, 2017). This session was followed by a Roundtable Event which built on the approach elements shared by presenters during the scientific session. The intent of the roundtable was to review the presented decision tree approach for botanical evaluation from the scientific session, and use the roundtable panel and participants as follows:

- Discuss and provide perspective on the decision tree approach (i.e. is there agreement in the key elements that are needed to build a robust botanical safety evaluation)
- Highlight and debate any vulnerabilities in the decision tree approach
- Share additional perspective to ensure this end-to-end safety approach is sufficient and actionable