Toxicology and safety assessment of essential oils.

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A major task of toxicology is to recognize the risk imposed on human and environmental health by industrial chemicals, medicinal products, botanicals, food additives and contaminants, cosmetics etc. (risk characterization) and thereby, to provide a rational basis for therapy or health protection (risk management). To ensure a high degree of reliability and adequacy of procedures and data applied for chemical safety assessment (CSA), a large body of internationally recognized guidelines has been developed, the details of which may differ depending on the legal framework of the respective political entities such as the European Union. In principle, a toxicological risk characterization links the following information: EXPOSURE ASSESSMENT: essential oils are plant constituents, in general complex mixtures of lipophilic compounds such terpenes and phenylpropanoids. Notably, exposure assessment of essential oil preparations should take into account that their eventual chemical composition may be markedly affected by geographical and environmental factors. As constituents of parfums, cosmetics, plant food supplements, food flavourings etc. essential oils are pervasive in everday life. In general, depending on the use pattern, intake can ensue via dermal, inhalatory or oral pathway; exposure of consumer or environment covers a wide dose/concentration range. HAZARD ASSESSMENT: identification of type of damage and establishing a dose-response relationship. Type and severity of toxic effects of essential oils -like any other chemical substance- depend on (physico)chemical properties, route of exposure and dose. Hazards caused by essential oils comprise a broad spectrum incl. local irritation, allergenic effects, photoxicity (e.g.limonene, turpentine, Bergamot oil). Based upon their lipophilicity, essential oils are readily absorbed by intact skin, respiratory or gastrointestinal tract and therefore, may also provoke systemic toxicity, for instance in nervous system, liver, reproductive organs. Key elements in establishing the toxicological profile of chemical substances or botanicals comprise: No-Observed-Adverse-Effect-Level (NOAEL), Lowest-Observed-Adverse-Effect-Level (LOAEL), Benchmark Dose (BMD), Mode of Action (MOA, e.g. thresholded vs non-thresholded effect). RISK CHARACTERIZATION: extrapolation of the likelihood that an adverse effect will become manifest in humans or environment under reasonably foreseeable conditions of use of a given chemical or mixture of substances; the risk is being quantified by comparing a given exposure level (dose/concentration) with effect criteria. In the present lecture, using pulegone, myristicin, linalool, safrole, limonene as examples, principles of the Margin of Safety (MOS)-, Margin of Exposure (MOE)- and Threshold of Toxicological Concern (TTC)-approach will be addressed. UNCERTAINTY ANALYSIS: a narrative description addressing the robustness (validity, relevance) of available data for exposure as well as hazard assessment. This is to allow a reasonable interpretation of the potential risk for human or environmental health.

Annotation: *retired from MUW

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