Risk assessment approach for E-cigarette flavours

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INTRODUCTION

Flavours are an important aspect of the e-cigarette sensory experience. The e-cigarette aerosol is generated by a heating coil vapourising the e-liquid. The vapourisation temperature has been estimated to reach up to 350°C [1], in the absence of higher temperatures reported in the e-liquid [2]. Our toxicological risk assessment approach to flavours considers both the flavour itself and the identification, measurement and risk assessment of any potential thermal breakdown and/or reaction products.

Exclusion criteria

Ingredients are excluded from use if they are:
- Non-threshold carcinogens
- Mutagens
- Genotoxins
- Reproductive and Developmental toxicants
- Respiratory sensitizers
- On the REACH list for Substances of Very High Concern (SVHC)
CMR status is assessed using IARC status and regulatory classifications from both FDA and the EU (harmonised and self-notified).

Risk Assessment Methodology

A risk assessment is performed for each ingredient separately. Natural flavourings are broken down into constituents based on compositions reported in the literature. When the data allow, a quantitative risk assessment is performed with separate derived No Effect Levels for systemic and local toxicity. If international scientific opinions (e.g. JECFA, EFSA, IARC) on the ingredients are available, these are relied upon for systemic toxicity evaluations, extrapolating to a different route of exposure. REACH guidance on risk assessment (7) is followed to extrapolate between species, exposure routes, exposure durations, etc. Published inhalation Toxicological Thresholds of Concern (TTCs) derived from a list of products relevant to consumer products are applied, e.g. Cramer class 1: 980 µg/day, Cramer class 3: 170 µg/day [6]. These TTCs are considered relevant for the flavouring ingredients, but not for other compounds found in the aerosol (see “TTCs” box).

Conclusions

A toxological risk assessment for e-cigarette flavours should incorporate consideration of both the ingoing flavour ingredients, as well as the resultant degradation/reaction compounds the consumer is actually exposed to in the aerosol. Ingredient selection should take account of the potential of the ingredients as their potential to cause thermal breakdown and reaction products.

Because of the wide range of flavouring compounds and their potential reaction and breakdown products, the chemical profile of the flavouring-related compounds in the aerosol should be investigated using non-targeted, broad screening methods. All ingredients and any compounds detected in the aerosol different to the formulation ingredients, should be risk assessed to ensure suitability for use in a heated, inhalation application.

References