# Risk Assessment of Three Smoke Flavoring Primary Products Currently Under Re-Evaluation by EFSA

A.C. Franzen, C.M. Thompson, G.P. Brorby, D.S. Wikoff, Z. Ilkbahar[1], C. Doepker
1 Kerry Inc., Naas, Ireland

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## Abstract:

Smoke flavorings are used in or on a variety of foods to impart a smoky taste and have many advantages compared to conventional smoking techniques. These flavors are traditionally used in/on meat, fish and cheeses and have been in use for centuries. The objective of this work was to determine the safety of three smoke flavoring primary products (SFPPs) (SF-002, SF-005, SF-006) which are used to produce smoke flavorings. These SFPPs are currently under re-evaluation in the European Union by European Food Safety Authority (EFSA) to have their existing authorizations to be renewed. The risk assessment was conducted using modified methodologies outlined in the EFSA (2021)'s *Scientific Guidance for the preparation of applications on smoke flavouring primary products*. This assessment involved evaluation of mixtures as a whole, as well as individual constituents.

The hazard evaluation was based on stepwise assessment first of the potential for genotoxicity, followed by other endpoints. Guideline-based micronucleus (OECD 474) and transgenic rodent assays (OECD 488) were conducted for each SFPP; results were negative, demonstrating a lack of concern for genotoxicity. For other endpoints, previously conducted 90-day studies (OECD 408) were available for each SFPP; the no observed adverse effect levels (NOAELs) from these studies ranged from 785 mg/kg-bw/day to 1,397 mg/kg-bw/day.

For the constituent-based assessment, a robust analytical characterization was performed resulting in the identification and quantification of over 95% of the volatile fraction of the smoke flavors; SF-002 and SF-006 had 48 constituents and SF-005 had 49 constituents. Systematic literature searching was conducted for each constituent following a tiered approach, focusing on EFSA evaluations, other European or global authoritative bodies, genotoxicity databases and primary literature to identify any available genotoxicity data. For constituents that had available testing data, a hazard-based assessment was performed (SF-002=34, SF-005=39, SF-006=38). If no data were identified (SF-002=14, SF-005=10, SF-006=10) an in-silico assessment was performed using read-across and/or QSAR modeling. Of the identified constituents, none were determined to pose a genotoxic risk under the conditions of intended use when considered together in a risk-based analysis with the whole mixture data.

The exposure assessment involved a combination of consumption data from the European Union Comprehensive Food Consumption Database as well as use levels of the flavors for a variety of different foods. After utilizing EFSA's intake models (i.e., FAIM, DietEx), it was determined that FAIM is not as reliable as DietEx due to overly broad food categories that greatly overestimate exposure. Therefore, the most reliable exposure estimate, derived by DietEx, was 1.2 mg/kg-bw/day, 0.98 mg/kg-bw/day, and 0.96 mg/kg-bw/day for SF-002, SF-005 and SF-006 respectively.

MOS estimates were calculated using the NOAEL values from the 90-day studies and exposure estimates from DietEx, resulting in MOS values of 640 for SF-002, 1400 for SF-005 and 1400 for SF-006. Based on their MOS these smoke flavoring primary products are of no safety concern at their proposed use levels, consistent with EFSA's MOS of greater than 300. In conclusion, this risk assessment supports that the overall safety for these SFPPs continues to be demonstrated. This risk assessment also helps to inform risk-benefit considerations, particularly when comparing the robust safety profile of these SFPPs relative to lack of traditional safety data for conventional smoke.