SCIENTIFIC OPINION

Safety of smoke flavour Primary Product - Fumokomp

Scientific Opinion of the Panel on Food Contact Material, Enzymes, Flavourings and Processing Aids (CEF)

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

The European Food Safety Authority has been asked to provide scientific opinions on the safety of smoke flavouring Primary Products used or intended for use in or on foods. This opinion concerns one such smoke flavouring Primary Product, named Fumokomp.

The raw material consists of at least 85% beech (Fagus sylvatica L.) wood, the remaining portion is hornbeam (Carpinus betulus L.). The dried material is pyrolysed. The raw wood tar is subjected to a series of fractionated vacuum distillations. Information on key operational parameters has been provided. The Primary Product is obtained by combining appropriate distillate fractions.

The Primary Product is a solvent-free distillate. The total identified mass (92%) is in compliance with Commission Regulation (EC) 627/2006. Except for benzo[j]fluoranthene and cyclopenta[cd]pyrene, data on the concentrations of the polycyclic aromatic hydrocarbons (PAHs) listed in Annex 2 of the EFSA Guidance document have been provided. The analyses were performed by an external laboratory using a GC/MS-based method; experimental conditions but no validation or performance data were provided. Additional analyses using a validated method revealed the levels of benzo[a]pyrene and benzo[a]anthracene to be below their respective limits of 10 and 20 ug/kg given in Regulation (EC) No. 2065/2003 (EC, 2003).

The data provided on batch-to-batch variability and stability of the Primary Product were limited but considered acceptable by the Panel.

Fumokomp gave negative results in a bacterial reverse mutation assay performed in accordance with OECD Guideline 471, using Salmonella typhimurium TA98, TA100, TA1535, TA1537 and Escherichia coli WP2 uvrA, both in the absence and presence of S9. Negative results were also obtained in an in vitro mammalian chromosome aberration test carried out in Chinese hamster ovary cells in accordance


with OECD Guideline 471. Positive results were obtained in the mouse lymphoma L5178Y tk+/- assay, with and without S9, with increases of both large and small colonies, thus indicating the ability of the test material to induce genotoxic effects both at gene and chromosome level. However, an in vivo bone marrow micronucleus assay was negative and an in vivo rat liver unscheduled DNA synthesis test was also negative.

Overall it was concluded that Fumokomp is genotoxic in vitro, based on the results of a mammalian cell mutation assay, whereas two in vivo genotoxicity tests were negative and sufficient to eliminate the concerns over the in vitro genotoxicity.

In the 90-day rat dietary feeding study carried out at levels of 200 mg/kg and 400 mg/kg diet, equivalent to intakes of 10 and 20 mg/kg bw/day, the study authors concluded that the KHV smoke flavour preparation did not have any toxic effects at either dietary level. On this basis, the level of 400 mg Primary Product/kg diet appeared to be a NOAEL, equivalent to 20 mg/kg bw/day.

The Panel was unable to confirm this conclusion. The 90-day study in rats was carried out before GLP standards were introduced, the number of parameters investigated was limited, and the study report was only available as a summary. The Panel also noted that the identity of the material tested in the study is unknown. For these reasons, the Panel considered that the validity of the study could not be confirmed and hence the study was not used in the safety evaluation of Fumokomp.

In order to estimate dietary exposure to the Primary Product Fumokomp, the CEF Panel used two different methodologies developed by the Panel specifically for smoke flavourings. Dietary exposure estimates were calculated by assuming that the Primary Product is present at the normal or upper use levels provided by the applicant for the 18 food categories as outlined in Commission Regulation (EC) No 1565/2000.

Dietary exposure from all sources ranges from 0.13 to 0.20 mg/kg bw/day, when assuming that the Primary Product is present at the upper use levels, and from 0.08 to 0.13 mg/kg bw/day when normal use levels are considered.

When dietary exposure estimates are based on use in only traditionally smoked foods, dietary exposures ranges from 0.05 to 0.09 mg/kg bw/day when assuming that the Primary Product Fumokomp is present at the upper use levels, and from 0.03 to 0.06 mg/kg bw/day, when normal use levels are considered.

The Panel was unable to derive a NOAEL for Fumokomp and consequently, no margins of safety have been calculated.

The Panel concluded that the toxicological data do not enable the safety of Fumokomp to be established.

**KEY WORDS**

Smoke flavouring, Primary Product, Fumokomp.