

SCIENTIFIC OPINION

Safety of smoke flavour Primary Product - Scansmoke PB 1110 ¹

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

(Question No EFSA-Q-2005-261)

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PANEL MEMBERS

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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 a smoke flavouring Primary Product, named Scansmoke PB 1110.

The Primary Product Scansmoke PB 1110 is obtained from mixed wood species: 90 % beech (*Fagus sylvatica*) and 10 % oak (*Quercus alba*).

The production of Scansmoke PB 1110 comprises the following steps: (i) adjustment of the moisture content, (ii) smouldering of the wood under controlled conditions, (iii) separation of the primary tar, (iv) condensing of the released smoke, (v) separation of the liquid phase from residual tar, (vi) distillation and extraction of the liquid smoke condensate and the primary tar, (vii) mixing of the two fractions. Essential parameters of the process have been provided by the applicant.

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Scansmoke PB 1110 contains 50 wt. % of water as solvent. The mass of the volatile fraction amounts to 25 wt. %; 88 % of the volatile fraction has been identified. The mass of identified constituents (22 wt. %) corresponds to 44 % of the solvent-free mass. The Panel noted that this is lower than the proportion of at least 50 % of the solvent-free mass required to be identified and quantified according to Commission Regulation (EC) 627/2006 (EC, 2006). However, taking into account the uncertainties in GC/FID quantitation and that a large proportion of the volatile fraction was identified, the Panel considered the value acceptable. Except for benzo[*j*]fluoranthene, the concentrations of the polycyclic aromatic hydrocarbons (PAHs) listed in Annex 2 of the EFSA Guidance document have been provided. In addition, the contents of fluorene, phenanthrene, anthracene, fluoranthene and pyrene have been determined. The levels of benzo[*a*]pyrene and benzo[*a*]anthracene are below their respective limits of 10 and 20 µg/kg given in Regulation (EC) No. 2065/2003 (EC, 2003). Scansmoke PB 1110 had consistently low levels of PAHs in the batches tested. The Panel considered the data provided on the batch-to-batch variability and on the stability of the Primary Product as sufficient.

Normal use levels of the Primary Product proposed by the applicant range between 1 g/kg food (ready-to-eat savouries, composite foods) and 5 g/kg food (dairy products, processed vegetables, meat and meat products, salts, spices, soups, salads, protein products and composite foods). Dietary exposure for the Primary Product, as estimated by the applicant, was 14 mg/kg bw/per day.

In order to estimate dietary exposure to the Primary Product Scansmoke PB 1110, 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 Scansmoke PB 1110 is present at the normal or upper use levels provided by the applicant for the 18 food categories as outlined in Commission Regulation (EC). Dietary exposure from all sources range from 21.8 to 30.0 mg/kg bw/day, when assuming that the Primary Product Scansmoke PB 1110 is present at the upper use levels, and from 16.2 to 28.3 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 range from 8.3 to 14.5 mg/kg bw/day, when assuming that the Primary Product Scansmoke PB 1110 is present at the upper use levels, and from 6.7 to 12.1 mg/kg bw/day, when normal use levels are considered.

Genotoxicity studies conducted on Scansmoke PB 1110 included 3 *in vitro* studies (bacterial reverse mutation test, mammalian cell gene mutation assay and chromosome aberration test) and two *in vivo* studies (mouse bone marrow micronucleus test and a UDS test).

In vitro genotoxicity tests with Scansmoke PB 1110 in bacteria showed essentially negative results in the *S. typhimurium* reverse mutation assay.

Positive results were obtained *in vitro* in the mouse lymphoma assay, indicating the ability of Scansmoke PB 1110 to induce genotoxic effects at gene and chromosome level.

Negative results were obtained in the *in vitro* chromosome aberration test in CHO cells treated with Scansmoke PB 1110, however at very low concentrations.

The *in vivo* mouse bone marrow micronucleus assay was negative, without significant depression of the PCE:NCE ratio.

Scansmoke PB 1110 has not shown any evidence of causing unscheduled DNA synthesis (UDS) in hepatocytes of CrI:CD_{TM}(SD)IGS BR (Sprague Dawley) rats following oral administration.

Overall, it is concluded that Scansmoke PB 1110 is genotoxic *in vitro* in the mouse lymphoma assay, whereas two *in vivo* genotoxicity tests are negative and sufficient to eliminate the concerns over the *in vitro* genotoxicity.

The Primary Product was investigated in a 90-day study in Wistar rats performed according to OECD guidelines. Scansmoke PB 1110 was given at levels of 0 (control), 1000, 3000 and 9000 mg/kg diet. The NOAEL was 9000 mg/kg diet, the highest dose level tested, which, according to calculations made by the applicant, amounted to 689 mg/kg bw/day in male and 975 mg/kg bw/day in female rats.

Based on these data it is concluded that when assuming that the Primary Product Scansmoke PB 1110 is present at the normal or upper use levels provided by the applicant for the 18 food categories, the margins of safety as compared to the NOAEL of 700 mg/kg bw/day, derived from the 90-day toxicity study with Scansmoke PB 1110 in rats, amounts to 23 - 32 for the intake estimates based on the upper use levels and to 25 - 43 when normal use levels are considered.

When assuming the use of Primary Product Scansmoke PB 1110 in traditionally smoked products only, the margins of safety would amount to 48 - 84 for the intake estimates based on the upper use levels and to 58 - 104 when normal use levels are considered.

Given i) the fact that these margins of safety are based on a 90-day toxicity study, ii) the absence of data on reproduction and developmental toxicity and iii) the absence of long term studies, it is concluded that the uses and use levels of Primary Product Scansmoke PB 1110 would require a larger margin of safety. The Panel concludes that the margin of safety is insufficient and that the use of Primary Product Scansmoke PB 1110 at the proposed uses and use levels is of safety concern.

To decide whether despite the low margins of safety the use of Primary Product Scansmoke PB 1110 might be approved for traditionally smoked products, at use levels specified, to replace smoking, is outside the remit of the Panel.

Key words: Smoke flavouring, Primary Product, Scansmoke PB 1110.