EN E-007087/2011 Answer given by Mr Dalli on behalf of the Commission (18.8.2011)

1 and 4. In order to protect public health, maximum levels for polycyclic aromatic hydrocarbons in foodstuffs are laid down in Regulation (EC) 1881/2006¹. These levels apply also to foodstuffs where smoke flavourings are used.

Moreover, smoke flavourings should undergo a safety assessment and should comply with the conditions for their production as laid down in Regulation (EC) 2065/2003² despite the fact that their use is generally considered to be less of a health concern (due to fractionation and purification processes) than the traditional smoking process.

Of the primary products mentioned in the question, only FF-B was found to be weakly genotoxic *in vivo*. Consequently, the petitioner withdrew its application and the primary product, as well as derived products, were withdrawn from the market in 2007.

As for TRADISMOKE TM A and SCANSMOKE R909, *in vivo* genotoxicity tests were negative and sufficient to eliminate the concerns over the *in vitro* genotoxicity.

As for AM 01, the genotoxic potential could not be ruled out based on the information available at the time of EFSA's assessment³. In the meantime the petitioner carried out an *in vivo* Comet assay that should address the genotoxic potential of AM 01. On 14 July 2011 the Commission asked EFSA for a re-evaluation of AM 01 in the light of new information provided.

The Union list should be established after the completion of the safety assessment of all primary products for which sufficient information was submitted. Once EFSA has completed the evaluation of AM 01, the Commission will consider the outcome of the EFSA assessments, together with the Member States, in order to assess the different risk management options. According to the current state of play the Commission should adopt the first Union list of authorised primary products in the first guarter of 2012.

2 and 3. In some specific products (e.g. chocolate) smoke flavourings are used as a component of complex flavourings. In this case, smoke flavourings are used in very low quantities and do not impart a smoky flavour.

Rules on the labelling of flavourings are laid down in Directive 2000/13/EC⁴. The use of flavourings must not mislead the consumer and their presence in food should be appropriately indicated. The consumer should not be confused by labelling of a smoke flavouring if the smoke flavouring does not impart a smoke taste and therefore this taste is not identifiable in the product.

¹ OJ L 364, 20.12.2006

² OJ L 309, 26.11.2003

³ EFSA Journal 2010; 8(1):1396

⁴ OJ L 109, 6.5.2000