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SCIENTIFIC OPINION

Dietary exposure assessment methods for smoke flavouring Primary Products[1]

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

(Question No EFSA-Q-2008-402)

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SUMMARY

A standard method specifically designed for assessing the dietary exposure to smoke flavourings does not exist. The Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF) therefore evaluated the suitability of three methodologies presently applied to the dietary exposure assessment of flavouring substances for smoke flavourings. These are the Maximised Survey-derived Daily Intake (MSDI), the Single Portion Exposure Technique (SPET), and the Theoretical Added Maximum Daily Intake and its modified version (TAMDI/mTAMDI). In addition, the Panel developed two new methodologies specifically relevant for smoke flavourings and allowing the evaluation of the impact on exposure of authorizing these substances only in traditionally smoked food products. One of them, called Smoke Flavouring Theoretical Added Maximum Daily Intake (SMK-TAMDI), is based on an adaptation of the TAMDI approach to make it more specifically relevant for the use of smoke flavourings in or on foods. The second, called Smoke Flavouring EPIC model (SMK-EPIC), makes use of the information on the consumption of smoked foods available from the European Prospective Investigation into Cancer and Nutrition (EPIC) study. Normal and Upper Use Levels provided by the applicants in each of the 18 food categories as outlined in Commission regulation (EC) No 1565/2000 were used to assess the exposure. Dietary exposure estimates assessed with the five different methodologies resulted in the same order of magnitude for all smoke flavouring under evaluation. The CEF Panel concluded that the SMK-TAMDI and SMK-EPIC methods were suitable for assessing the dietary exposure to

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smoke flavourings used or intended for use in or on foods. The SMK-TAMDI method, due to its calculation principles, will always yield exposure values equal to or higher than the SPET method. Due to the different scenarios taken into account by each of these methodologies, the CEF Panel suggested to estimate dietary exposure to smoke flavourings by means of Upper Use Levels, using the SMK-TAMDI and SMK-EPIC methods and to always use the highest value among these estimates when carrying out risk assessments to these products.

Key words: Smoke Flavouring, Primary Product, exposure assessment, Maximised Survey-derived Daily Intake (MSDI), Single Portion Exposure Technique (SPET), and the Theoretical Added Maximum Daily Intake and its modified version (TAMDI/mTAMDI), Smoke Flavouring Theoretical Added Maximum Daily Intake (SMK-TAMDI), European Prospective Investigation into Cancer and Nutrition (EPIC), Smoke Flavouring EPIC model (SMK-EPIC).

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BACKGROUND

The European Food Safety Authority (EFSA) has been asked to provide scientific opinions on the safety of Smoke Flavouring Primary Products used or intended for use in or on foods. The Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in contact with Food (AFC) noted that there is no standard method specifically designed for the dietary exposure assessment of smoke flavourings.

In particular, smoke flavourings present significant differences with respect to the other flavouring substances. These differences are mainly in the concentration levels used - smoke flavourings are complex mixtures and are generally used at significantly higher concentrations than the flavourings which are single substances - and in the categories of food products to which these substances are added. In particular, smoke flavourings are traditionally used in meat and fish products and are commonly not added with the other flavouring substances.

Three methodologies are presently applied to the dietary exposure assessment of flavouring substances by EFSA and/or the Joint FAO/WHO Expert Committee on Food Additives (JECFA). These comprise the Maximised Survey-derived Daily Intake (MSDI), the Single Portion Exposure Technique (SPET), and the Theoretical Added Maximum Daily Intake and its modified version (TAMDI/mTAMDI).

Because of the above mentioned differences, the methods currently used for the assessment of dietary exposure to flavourings could be considered not to be fully appropriate for smoke flavourings.

TERMS OF REFERENCE

In accordance with Article 29 (1) (b) of Regulation No 178/2002, the European Food Safety Authority asks its Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in contact with Food (AFC) to assess the suitability of the three presently applied methodologies to the dietary exposure assessment of flavouring substances for their use for smoke flavouring primary products and if found appropriate to adapt the existing methods or develop new ones.

The Scientific Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF) has taken over this mandate.

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ASSESSMENT

1. Introduction

The evaluation of Smoke Flavouring Primary Products by EFSA started after the deadline of 16 June 2005 for the submission of a valid application as set out in Article 20 (a) of Regulation (EC) No 2065/2003 of the European Parliament and of the Council of 10 November 2003 on smoke flavourings used or intended for use in or on foods.

EFSA received 16 applications (named SMK No 1-16), each of them referring to a different smoke flavouring. Of these 16, two were not accepted, three were withdrawn by the applicant and for one the AFC Panel issued a risk assessment opinion (EFSA, 2007). The assessment of exposure calculated in the present opinion refers to the remaining 11 applications currently under EFSA evaluation (see Annex 2).

As a first approach, the Panel evaluated three methodologies presently applied by EFSA and/or the Joint FAO/WHO Expert Committee on Food Additives (JECFA) to the dietary exposure assessment of flavouring substances regarding their suitability for smoke flavourings. These comprise the Maximised Survey-Derived Intake (MSDI), the Single Portion Exposure Technique (SPET), and the Theoretical Added Maximum Daily Intake and its modified version (TAMDI/ mTAMDI).

In addition, the Panel developed two new methodologies. One of them, called Smoke Flavouring Theoretical Added Maximum Daily Intake (SMK-TAMDI), is based on an adaptation of the TAMDI approach to make it more specifically relevant for the use of smoke flavourings in or on foods. The second, called Smoke Flavouring EPIC model (SMK-EPIC), makes use of the information on the consumption of smoked foods available from the European Prospective Investigation into Cancer and Nutrition (EPIC) study. This document outlines the principles underlying these methodologies and presents their application to the dietary exposure assessment of the smoke flavourings under evaluation.

2. Use levels

Normal and upper use levels provided by the applicants for the smoke flavourings under evaluation in each of the 18 food categories as outlined in Commission regulation (EC) No 1565/2000 (EC, 2000) are reported in Tables 1 and 2, respectively.
It is noteworthy that for many food categories the use levels are the same or very similar. Significantly lower use levels have only been reported for SMK No 10 and SMK No16.

The exposure estimates that are based on food consumption data always assume that the smoke flavouring is present at the Normal or Upper Use Levels provided by the applicants.
Only for food category 12 “Salts, spices, soups, sauces, salads, protein products etc.” the applicants were asked to provide Normal and Upper Use Levels for each of the subcategories. This level of detail was considered necessary to avoid an overestimation of exposure. This category is particularly heterogeneous because it contains products being significantly different in terms of consumption. For example, the standard portion sizes established by JECFA (2006a; World Health Organisation, 2009) for the food products included in category 12 range from 1 g/day for spices to 200 g/day for soups. Therefore, when available, the Normal and Upper Use Levels for each of the subcategories belonging to the food category “Salts, spices, soups, sauces, salads, protein products etc.” were used in order to assess exposure. The Normal and Upper Use Levels for the food

category 12 “Salts, spices, soups, sauces, salads, protein products etc.” are reported in Table 3 and 4.
Normal and Upper Use Levels for the food category 16 ´composite food (e.g. casseroles, meat pies, mincemeat) – foods that could not be placed into categories 1-15’ are referred to the total amount of composite food itself (e.g. meat pie) and not to some of the ingredients contained in such composite food (e.g. meat in meat pie).

3. Methodologies presently applied to the dietary exposure assessment of flavouring substances

3.1. The Maximised Survey-derived Daily Intake (MSDI)

The Maximised Survey-derived Daily Intake (MSDI) method is used in the procedure developed by JECFA (JECFA, 1997) and has been adopted by the European Commission (EC, 2000) for the safety evaluation of flavouring substances. The MSDI method, also known as the “per capita x 10” approach, is based on poundage data of the flavour-industry (kg/year) adjusted to a per capita basis. Estimates obtained are often referred as “estimated daily per capita intakes”. Manufacturers are requested to exclude the use of flavouring substances in pharmaceutical, tobacco, and cosmetic products. Corrections are made for incomplete survey data by industry on the basis of an estimated “survey total response rate”, generally equal to 0.60. The dietary exposure is estimated for consumers only, assumed to be 10% of the population for all flavourings. The following formula is used:

$$MSDI_{(\mu g/capita/day)} = \frac{Annual\ \ production_{(kg)} \times 10^{9}_{(\mu g/kg)}}{Population\ of\ \ consumers \times Survey\ response\ rate \times 365_{(days)}}$$

The standard value of 60 kg body weight is used to assess exposure in mg/kg body weight.

Individual production volumes for the different smoke flavouring have not been provided. Therefore, it is not possible to use this method to assess the exposure of single smoke flavourings. Only one applicant (SMK No 7) gave an estimation of the overall annual production volume of smoke flavourings in Europe. According to this source, the world market for smoke flavours is currently approximately 53,000 t standard liquid smoke and 10-15,000 t smoke oils and powders. In Europe the market is estimated to be approximately 8-10,000 t liquid smoke and 2-3,000 t smoke powders and oils. These data were used to estimate the overall dietary exposure to all smoke flavourings by means of the MSDI method resulting in 23.8 mg per capita/day kg body weight (Table 5).

3.2. The Single Portion Exposure Technique (SPET)

At its 65th meeting, the JECFA considered how to improve the identification and assessment of flavouring substances for which the MSDI estimates may be substantially lower than the dietary exposures estimated from the anticipated average use levels in foods. The 65th meeting proposed that an *ad-hoc* Working Group be convened to further consider all relevant aspects of the introduction of an additional screening method based on use levels, to complement the MSDI. This Working Group explored various options and proposed the Single Portion Exposure Technique

(SPET) as an additional method of dietary exposure assessment to address the questions raised by previous Committees.

The SPET was developed and tested by the JECFA Committee at its 67th (JECFA, 2006b) and 68th (JECFA, 2007) meetings, respectively. It is based on flavour-industry recommended use levels for each flavouring substance in food categories, in combination with standard portion sizes (JECFA, 2006a; World Health Organisation, 2009). These standard portions are not supposed to reflect high food consumption amounts reported in national dietary surveys but have been taken by JECFA to represent the mean food consumption amount for consumers of those food categories, assuming daily consumption over a long period of time. For flavouring substances with usages in multiple food categories, only the food category resulting in the highest potential dietary exposure is considered. The standard value of 60 kg body weight is used to assess exposure in mg/kg body weight. This dietary exposure is taken to represent that of a regular consumer of a flavoured food, who is loyal to a specific product containing the specific flavour of interest.
In the 69th JECFA meeting (JECFA, 2008) the Committee concluded that SPET estimates would be included into the Procedure for all flavouring substances considered at future meetings of the Committee.

Dietary exposure estimates calculated by means of the SPET method, considering either Normal or Upper Use Levels, are reported for the smoke flavourings under evaluation in Tables 6 and 7, respectively. When assuming that the Primary Product is present at the Normal Use Levels, dietary exposure from all sources result in 0.1 mg /day kg body weight for the two Primary products for which significantly lower use levels have been provided (SMK No 10 and SMK No 16) whereas all others range from 1.7 to 16.7 mg/kg bw/day. The highest exposure of 25.0 mg/kg bw/day (SMK No 2) results when Upper Use Levels are considered.

3.3. The Theoretical Added Maximum Daily Intake and its modified version (TAMDI / mTAMDI)

The Theoretical Added Maximum Daily Intake (TAMDI) (Cadby, 1996) has been used by the Scientific Committee on Food (SCF) to assess exposure to single flavouring substances (Scientific Committee for Food, 1995). This method is likely to provide a conservative estimate of the actual exposure by most consumers because it assumes that a consumer will daily consume a fixed amount of flavoured solid foods (133.4 g/day) and liquids (324 g/day), with the following exceptions: a) candy, confectionery (27 g/day), b) condiments, seasonings (20 g/day), c) alcoholic beverages (20 g/day), d) soups, savouries (20 g/day), e) others, e.g. chewing gum (2 g/day). Moreover, the TAMDI method assumes that all these items always contain the flavouring substance under evaluation at its specified Upper Use Level. The standard value of 60 kg body weight is used to assess exposure in mg/kg body weight.

The seven food groups used in the TAMDI approach correspond to the 18 food categories as outlined in Commission Regulation (EC) No 1565/2000 (EC, 2000), as follows:
- “Beverages” correspond to food category 14.1
- “Foods” correspond to the food categories 1, 2, 3, 4.1, 4.2, 6, 7, 8, 9, 10, 13, and/or 16
- “Exception a” corresponds to food category 5 and 11
- “Exception b” corresponds to food category 15
- “Exception c” corresponds to food category 14.2
- “Exception d” corresponds to food category 12

- "Exception e" corresponds to others, e.g. chewing gum

The AFC Panel (EFSA, 2004) used a modified version of the TAMDI-approach based on Normal Use Levels (called mTAMDI) to screen and prioritise the flavouring substances according to the need for refined dietary exposure data.

Dietary exposure estimates, for all the smoke flavourings under evaluation, calculated by means of the mTAMDI (using the Normal Use Levels) and TAMDI (using the Upper Use Levels) methods are reported in Tables 8 and 9, respectively.

Dietary exposure calculated by means of the mTAMDI resulted below 0.1 mg day per kg body weight for the two Primary products presenting significantly lower use levels (SMK No 10 and SMK No 16) whereas all others range from 1.7 to 13.9 mg/kg bw/day. The highest exposure calculated by means of the TAMDI results in 16.8 mg/kg bw/day (SMK No 8 and SMK No 9) when Upper Use Levels are considered.

4. Methodologies specifically developed for the dietary exposure assessment of smoke flavourings

4.1. The Smoke Flavouring Theoretical Added Maximum Daily Intake (SMK-TAMDI)

The Smoke Flavouring Theoretical Added Maximum Daily Intake (SMK-TAMDI) is an adaptation of the TAMDI method and has been developed by the CEF Panel to specifically estimate the dietary exposure to smoke flavourings. As for the TAMDI, the SMK-TAMDI also assumes that the consumer will daily consume a fixed amount of flavoured solid foods and liquids and that these items will always contain the smoke flavouring under evaluation at its specified Upper Use Level. In the SMK-TAMDI a single group "Beverages" is used for liquids (alcoholic and non-alcoholic beverages) whereas solid foods are divided in two groups: 1) "Traditionally smoked solid foods" (comprising the following food categories: "Dairy products, excluding products of category 2", "Meat and meat products, including poultry and game" and "Fish and fish products, including molluscs, crustaceans and echinoderms") and 2) "Other solid foods not traditionally smoked" (containing all other food categories). Tables 10 and 11 report the 18 food categories as outlined in Commission Regulation (EC) No 1565/2000 (EC, 2000) according to the above mentioned 3 groups. The division of solid foods in two groups is particularly important since it allows evaluating the impact on dietary exposure of authorizing each single smoke flavour in traditionally non-smoked food products. In the SMK-TAMDI, the fixed amounts of flavoured solid foods and liquids used by the TAMDI are replaced by the portion sizes established by JECFA to assess the SPET (JECFA, 2006a; World Health Organisation, 2009) (Tables 10 and 11).

In the SMK-TAMDI, dietary exposure is based on use levels provided by the applicant in each of the 18 food categories as outlined in Commission Regulation (EC) No 1565/2000 (EC, 2000) in combination with the above mentioned standard portion sizes. Within the three food groups ("Beverages", "Traditionally smoked solid foods" and "Other solid foods not traditionally smoked"), only the food category resulting in the highest potential dietary exposure is considered. This latest procedure is the same as that used by the SPET method.

For each of the 3 food groups, the dietary exposure is taken to represent that of a regular consumer of one flavoured product among the group, who is loyal to a brand containing the specific flavour of interest at the upper use level.
The SMK-TAMDI is calculated by summing the highest potential dietary exposure for each of the three food groups ("Beverages", "Traditionally smoked food" and "Other solid foods not traditionally smoked"). Such an estimate, based on daily consumption of one single standard portion for each of the three groups, is likely to provide a conservative assessment of long-term average dietary exposure for consumers of smoke flavourings from both traditional and non traditional smoked products. The value of 60 kg body weight is used to assess exposure in mg/kg body weight.
Dietary exposure estimates calculated by means of the SMK-mTAMDI (using the Normal Use Levels) and SMK-TAMDI (using the Upper Use Levels) methods are reported for all the smoke flavourings under evaluation in Tables 10 and 11, respectively.
Dietary exposure calculated by means of the SMK-mTAMDI results in 0.13 mg/kg bw/day for the two Primary products presenting significantly lower use levels (SMK No 10 and SMK No 16) whereas all others range from 2.5 to 28.3 mg/kg bw/day. The highest exposure calculated by means of the SMK-TAMDI results in 35.0 mg/kg bw/day (SMK No 6) when Upper Use Levels are considered.

Dietary exposure to the 11 smoke flavourings from traditionally smoked food products estimated by means of the SMK-TAMDI range from 13 to 40% and from 14 to 39% of the overall dietary exposure when using Normal and Upper Use Levels, respectively.

4.2. Smoke Flavouring EPIC model (SMK-EPIC)

A significant source of uncertainty in the estimation of the dietary exposure to food constituents based on food consumption databases is introduced by the difficulty in matching the food descriptions for which consumption data are required for exposure assessments with the food descriptors present in food consumption databases. This is a crucial problem also in the case of smoke flavourings since most National food consumption surveys are conducted primarily to assess the nutrient intake of the population and therefore use food coding schemes that do not differentiate between smoked and non- smoked foods and beverages.
The food consumption survey carried out within the European Prospective Investigation into Cancer and Nutrition (EPIC) project is among the few cases in which the consumption levels of "smoked meat" were assessed and published (Linseisen *et al*., 2006). Moreover, the same study provides average consumption levels for the other products susceptible to be smoked, such as "dairy products" (Hjartaker *et al*., 2002) and "fish and fish products" (Welch *et al*., 2002). Unfortunately, for all these other products, specific information on the consumption of the smoked variety is not available. It is noteworthy that the EPIC study offers the opportunity to study the diversity of food habits in Europe because it includes 35,955 subjects (22,924 women and 13,031 men) who participated in the EPIC calibration study between 1995 and 1998 (except Norway: 1999–2000) from 27 study centres in 10 European countries (France, Italy, Spain, Greece, The Netherlands, the United Kingdom, Germany, Denmark, Sweden, Norway). The age of the participants ranged from 35 to 74 years at recruitment. All consumption data were collected within this study with the same protocol: one 24-hour recall.
Detailed information on type and preparation of the processed meat consumed is only available for males and females of a subset of EPIC participants (Spain, Italy, Germany, The Netherlands, United Kingdom and Sweden). The average and Standard Error of the Mean (SEM) consumption of total processed meat and smoked meat for males are reported in Table 12. In order to provide a simple

and conservative picture, only data referring to males are presented here because they present higher consumption values in almost all the countries. In general, the consumption of processed meat is clearly higher in the EPIC cohorts of central and northern Europe than in the southern cohorts. Moreover, smoking of processed meat was more often applied in central and northern countries than in the Italian or Spanish centres. In particular, smoked meat represents more than 50% of the total meat consumed in Germany, The Netherlands and Sweden. The average consumption of smoked meat was particularly high in the male population of the study centres in Potsdam (Germany) (52 g/day), Umea (Sweden) (44 g/day) and Bilthoven (The Netherlands) (38 g/day). In all these centres the consumption of smoked meat exceeds, on average, the consumption of both "fish and fish products" (either smoked or not) and "cheese" (either smoked or not) (Table 12).
The Smoke Flavouring EPIC model (SMK-EPIC) calculates the potential cumulative dietary exposure to smoke flavourings from all possible sources using the consumption data for the male population of Potsdam (Germany). Based on the EPIC data this population was used because it represents the most conservative among the presented European cases regarding the consumption of smoked meat, fish and cheese. The potential dietary exposure estimated is that of a hypothetical high consumer of smoked meat who is also an average consumer of the other traditionally smoked foods and an occasional consumer of smoked foods or beverages from each of the other categories as outlined in the Commission Regulation (EC, 2000).

The following assumptions were made:

a the 18 food categories as outlined in Commission Regulation (EC) No 1565/2000 (EC, 2000) are organised in the following three groups: 1) "Beverages" used for liquids (alcoholic and non-alcoholic beverages); 2) "Traditionally smoked solid foods" (comprising "Dairy products, excluding products of category 2", "Meat and meat products, including poultry and game" and "Fish and fish products, including molluscs, crustaceans and echinoderms") and 3) "Other solid foods not traditionally smoked" (containing all remaining food categories);
b the Lognormal distribution is used in order to estimate the high consumption levels (95^{th} percentile) of "Smoked meat" for each centre by using the corresponding average, SEM and number of subjects reported in the EPIC publication;
c the average consumption of "Smoked fish and fish products" is estimated by assuming that the ratio between the average consumption of "Smoked fish and fish products" and "Fish and fish products" is equal to the ratio between the average consumption of "Smoked meat" and "Processed meat";
d the average consumption of "Smoked cheese" is estimated by assuming that the ratio between the average consumption of "Smoked cheese" and "Cheese" is equal to the ratio between the average consumption of "Smoked meat" and "Processed meat";
e the occasional consumption of all "Foods and beverages not traditionally smoked" was estimated based on the hypothesis that one standard portion, based on those reported by JECFA (2006a) in the latest call for data for evaluation of flavouring agents, is consumed each week;
f the standard value of 60 kg body weight is used to assess exposure in mg/kg body weight.

Cumulative dietary exposure estimates for all smoke flavourings under evaluation calculated using the SMK-EPIC model and the Normal and Upper Use Levels are reported in Tables 13 and 14, respectively.
When assuming that the Primary Product is present at the Normal Use Levels, dietary exposure from all sources results below 0.1 mg day per kg body weight for the two Primary products presenting significantly lower use levels (SMK No 10 and SMK No 16) whereas all others range

from 0.8 to 16.2 mg/kg bw/day. The highest exposure results in 23.9 mg/kg bw/day (SMK No 8 and SMK No 9) when Upper Use Levels are considered.
When using the SMK-EPIC, dietary exposure to the 11 smoke flavourings from traditionally smoked food products range from 45 to 86% and from 52 to 85% of the overall dietary exposure when using Normal and Upper Use Levels, respectively.

5. Dietary exposure estimates calculated by the applicants

Only for 6 of the 11 Primary products under evaluation dietary exposure was also assessed by the applicants using a variety of methods and assumptions. None of these was considered as suitable for the standard assessment of smoke flavourings. In most of these cases the Upper Use Levels were used; these estimates are reported in Tables 15 and 16. When the applicant presented more than one dietary exposure estimate, the highest value was reported in the above mentioned tables.
Dietary exposure estimated by the applicant is equal to 0.08 mg/kg bw/day for the application 16, the only case in which Normal Use Levels were used, whereas it ranges from 2.6 to 30.0 mg/kg bw/day for the other five applications.

6. Discussion

The methods currently used by JECFA and EFSA to estimate dietary exposure to flavouring substances are the MSDI, mTAMDI and SPET. The MSDI method uses poundage data but the annual production volumes for the individual smoke flavourings are not currently available. Therefore, it is not possible to use this method to assess the exposure of single smoke flavourings. Moreover, the MSDI method has been designed to estimate dietary exposure of single flavouring substances commercialised in Europe by different producers whereas each smoke flavouring Primary Product is a unique mixture of different substances and is produced by a unique company. Moreover it is unlikely that each of these companies sells its product all over Europe. In order to calculate the MSDI it was basically assumed that all the liquid smoke sold in Europe is produced by a single company. The MSDI can therefore only be used to provide a rough estimate of the overall exposure for smoke flavourings.

On the other hand, the basic assumptions of the TAMDI method and its modified version (mTAMDI) are aimed at assessing the exposure to flavouring substances generally not used in meat and fish, the traditionally smoked products. In particular, the quantities of foods and beverages considered in such a method were initially derived from consumption data of foods and beverages likely to contain intense sweeteners (Codex Alimentarius, 1989). The use of such quantities in order to assess exposure to smoke flavourings is therefore questionable.

The SPET is therefore the only methodology presently applied to the dietary exposure assessment of flavouring substances also suitable for smoke flavourings. However, this method provides an estimate of dietary exposure for an individual who daily consumes a standard portion of only one specific food product containing the flavouring substance and does not reflect high levels of food consumption reported in national dietary surveys. Moreover it does not differentiate the exposure from traditionally smoked food products.

Exposure estimates calculated by means of the SPET will always be lower or equal to those assessed by means of the SMK-TAMDI. The two methods make use of the same data in terms of standard portions and usage levels but the SMK-TAMDI estimates cumulative dietary exposure from 3 different food categories, one for each group, whereas only one of the categories is considered in the SPET approach.

The CEF Panel considered SMK-TAMDI and SMK-EPIC as suitable methods for assessing dietary exposure to smoke flavourings in a conservative way. In general terms, it is not possible to prefer one method to the other since they are based on significantly different assumptions made for estimating the consumption patterns and therefore represent different scenarios of exposure. The SMK-TAMDI is taken to represent that of a regular consumer (one portion per day) of one flavoured product among each of the 3 food groups ("Beverages", "Traditionally smoked food" and "Other solid foods not traditionally smoked"). The SMK-EPIC method utilises food consumption data from the EPIC dietary survey in order to estimate a hypothetical high consumer of smoked meat (the most consumed traditionally smoked food) who is also assumed to be a regular consumer of all other possible sources of dietary exposure to smoke flavourings. Moreover, it is important to note that the two methods developed *ad hoc* by the CEF Panel for the specific case of smoke flavourings, the SMK-TAMDI and SMK-EPIC, permit to evaluate the impact on dietary exposure of authorizing the Primary Product only in specific food groups, such as traditionally smoked food products.

Children, because of their higher food consumption rates per kg body weight, are generally expected to have a higher relative risk due to the higher exposure level and are therefore a susceptible subset of the population (Kroes et al., 2002). None of the methods presented in this opinion specifically takes into consideration the potential dietary exposure of children to smoke flavourings. The CEF Panel did not expect smoke flavourings to be added to foods specifically designed for infants (0 – 12 months) and small children (12 – 36 months). Therefore, no specific exposure assessment was performed considering these products.

The CEF Panel also considered that children consuming "regular foods" are unlikely to consume higher amounts of foods to which smoke flavourings may be added than adults per kg body weight. Unfortunately this statement cannot be proven since there are few consumption data for children available in the public literature and none of the dietary surveys conducted on this population group allowed to estimate the consumption of smoked foods as in the EPIC study. The CEF Panel considered that dietary exposure to smoke flavourings in children is unlikely to be higher than that estimated for adults, due to the conservative assumptions made in each of the methods.

All dietary exposure estimates calculated using the Normal and Upper use Levels are reported in Tables 15 and 16, respectively. When available, exposure estimates calculated by the applicant are also reported. Despite the different approaches followed, dietary exposure estimates assessed by means of the above described methodologies result in the same order of magnitude for all smoke flavourings under evaluation.

CONCLUSIONS

The CEF Panel concludes that the specially designed SMK-TAMDI and SMK-EPIC methods are suitable for assessing the dietary exposure to smoke flavourings used or intended for use in or on foods. The SMK-TAMDI method, due to its calculation principles, will always yield exposure values equal to or higher than the SPET method. Due to the different scenarios taken into account by each of these methodologies, the CEF Panel suggests to estimate dietary exposure to smoke flavourings by means of Upper Use Levels, using the SMK-TAMDI and SMK-EPIC methods and to always use the highest value among these estimates when carrying out risk assessments to these products.

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GLOSSARY / ABBREVIATIONS

AFC	Scientific Panel on Additives, Flavourings, Processing aids and Materials in Contact with Food.
bw	body weight
CEF	Scientific Panel on Food Contact Materials, Flavourings, Enzymes and Processing aids
EC	European Commission
EFSA	European Food Safety Authority
EPIC	European Prospective Investigation into Cancer and Nutrition
JECFA	Joint FAO/WHO Expert Committee on Food Additives
MSDI	Maximised Survey-derived Daily Intake
mTAMDI	modified Theoretical Added Maximum Daily Intake
SCF	Scientific Committee on Food
SEM	Standard Error of the Mean
SMK No	SMK No 1-16 refer to the applications 1-16 (see Annex 1)
SMK-EPIC	Smoke Flavouring EPIC model
SMK-mTAMDI	modified Smoke Flavouring Theoretical Added Maximum Daily Intake
SMK-TAMDI	Smoke Flavouring Theoretical Added Maximum Daily Intake
SPET	Single Portion Exposure Technique
TAMDI	Theoretical Added Maximum Daily Intake
WHO	World Heath Organisation

APPENDICES

ANNEX 1.

Table 1 - **Normal Use Levels for the smoke flavourings[2] in the 18 food categories as outlined in Commission Regulation No 1565/2000 (EC, 2000)**

Groups	Food categories		Normal use level per APPLICATION (g/kg)										
			2	4	6	7	8	9	10	13	14	15	16
Traditionally smoked solid foods	1	Dairy products, excluding products of category 2	0	0	5*	0.5*	2.5	2.5	0.015	0	1.5	2.5	0.007
	8	Meat and meat products, including poultry and game	1	3	4§	0.05§	2.5	2.5	0.02	4	2.5	2	0.016
	9	Fish and fish products, including molluscs, crustaceans and echinoderms	1	3	4§	0.05§	2.5	2.5	0.02	0	1.5	2	0
Other solid foods not traditionally smoked	2	Fats and oils and fat emulsions (type water-in-oil)	1	0	0	0	2.5	2.5	0.02	0	0	1.5	0
	3	Edible ices, including sherbet and sorbet	0	0	0	0	0	0	0	0	0	0	0
	4.1	Processed fruits	0	0	0	0	0	0	0	0	1.5	0	0
	4.2	Processed vegetables (including mushrooms & fungi, roots & tubers, pulses & legumes) and nuts and seeds	0	3*	5*	0.5*	1.2	1.2	0	0	1.5	0	0
	5	Confectionery	0	0	1*	0.5*	1.2	1.2	0	0	0	0	0
	6	Cereals and cereal products, including flours & starches from roots & tubers, pulses & legumes, excluding bakery	0	0	0	0	1.2	1.2	0	0	0	1.5	0
	7	Bakery wares	0	0	1	0.5*	2.5	2.5	0	0	0	1.5	0
	10	Egg and egg products	0	0	0	0	1.2	1.2	0	0	0	0	0
	11	Sweeteners, including honey	0	0	0	0	0	0	0	0	0	0	0
	12	Salts, spices, soups, sauces, salads, protein products etc.	1	4*	5*	1*	2.5	2.5	0.015	3	1.5	2.5	0.018
	13	Foodstuffs intended for particular nutritional uses	0	0	0	0	0	0	0	0	0	0	0
	15	Ready-to-eat savouries	1	3	1	0.05§	2.5	2.5	0.02	0	1	1.5	0.09
	16	Composite foods (e.g. casseroles, meat pies, mincemeat) - foods that could not be placed in categories 1 – 15	1	0.99	0.33	0.003	0.2	0.2	0.02	0	1.5	2	0
Beverages	14.1	Non-alcoholic ("soft") beverages, excl. dairy products	0.1	0	0	0	0.1	0.1	0	0	0	0	0
	14.2	Alcoholic beverages, incl. alcohol-free and low-alcoholic counterparts	0.1	1*	1*	0.1*	0.05	0.05	0	0	0	2.5	0

* The Upper use level is here used because the applicant declared to be unable to provide a Normal use level.
§ The applicant provided a range for the Normal use level instead of a single value, the highest figure in the range is here used.

[2] Based on information provided by the applicants.

Table 2 - **Upper Use Levels for the smoke flavourings[3] in the 18 food categories as outlined in Commission Regulation No 1565/2000 (EC, 2000)**

Groups	Food categories		Upper use level per APPLICATION (g/kg)										
			2	**4**	**6**	**7**	**8**	**9**	**10**	**13**	**14**	**15**	**16**
Traditionally smoked solid foods	1	Dairy products, excluding products of category 2	0	0	5	0.5	5	5	0.03	0	4	3	0.03
	8	Meat and meat products, including poultry and game	5	4	5	1.5	5	5	0.03	5	5	3	0.09
	9	Fish and fish products, including molluscs, crustaceans and echinoderms	5	4	5	1.5	5	5	0.03	0	5	3	0
Other solid foods not traditionally smoked	2	Fats and oils and fat emulsions (type water-in-oil)	1*	0	0	0	5	5	0.03	0	0	3	0
	3	Edible ices, including sherbet and sorbet	0	0	0	0	0	0	0	0	0	0	0
	4.1	Processed fruits	0	0	0	0	0	0	0	0	5	0	0
	4.2	Processed vegetables (including mushrooms & fungi, roots & tubers, pulses & legumes) and nuts and seeds	0	3	5	0.5	2.5	2.5	0	0	5	0	0
	5	Confectionery	0	0	1	0.5	2.5	2.5	0	0	0	0	0
	6	Cereals and cereal products, including flours & starches from roots & tubers, pulses & legumes, excluding bakery	0	0	0	0	2.5	2.5	0	0	0	3	0
	7	Bakery wares	0	0	1	0.5	5	5	0	0	0	3	0
	10	Egg and egg products	0	0	0	0	2.5	2.5	0	0	0	0	0
	11	Sweeteners, including honey	0	0	0	0	0	0	0	0	0	0	0
	12	Salts, spices, soups, sauces, salads, protein products etc.	5	4	5	1	5	5	0.03	4	5	3	1
	13	Foodstuffs intended for particular nutritional uses	0	0	0	0	0	0	0	0	0	0	0
	15	Ready-to-eat savouries	5	4	5	1.5	5	5	0.03	0	4	3	0.45
	16	Composite foods (e.g. casseroles, meat pies, mincemeat) - foods that could not be placed in categories 1 – 15	5	1.33	1.65	0.5	3	3	0.03	0	4	3	0
Beverages	14.1	Non-alcoholic ("soft") beverages, excl. dairy products	0.1*	0	0	0	0.2	0.2	0	0	0	0	0
	14.2	Alcoholic beverages, incl. alcohol-free and low-alcoholic counterparts	0.1*	1	1	0.1	0.1	0.1	0	0	0	3	0

* The Upper use level is here supposed equal to the Normal use level since the applicant provided an Upper use level lower than the Normal one.

[3] Based on information provided by the applicants.

Table 3 - **Normal Use Levels for all smoke flavourings under evaluation in each of the food products in the category "12. Salts, spices, soups, sauces, salads, protein products etc"**

12. Salts, spices, soups, sauces, salads, protein products etc.		Normal use level per APPLICATION (g/kg)										
		2	**4**	**6**	**7**	**8**	**9**	**10**	**13**	**14**	**15**	**16**
12.1	Salt and salt substitutes	0	0	0	0	0	0	0.02	0	0	1.5	0
12.2	Herbs, spices, seasonings and condiments	20	4*	2*	0.173*	2.5	2	0.02	0	1.5	1	0.5
12.3	Vinegars	0	0	0	0	0	0	0.015	0	0	0	0
12.4	Mustards	0	0	0	0	0	0	0.02	0	0	0	0
12.5	Soups and broths	0	2*	1*	0.005*	2.5	2.5	0.015	3	1	2.5	0.01
12.6	Sauces and like products	0.5	2*	1*	0.005*	2.5	2.5	0.02	3	1.5	0	0.031
12.7.1	Salads (e.g. macaroni salad, potato salad)	0	0	0	0	2.5	2.5	0.02	0	0	0	0
12.7.2	Sandwich spreads excluding cocoa- and nut-based spreads	0	0	0	0	2.5	2.5	0.02	0	0	0	0.3
12.8	Yeast and like products	0	0	0	0	5	5	0.02	0	0	0	0
12.9	Protein products	0	0	0	0	5	5	0.02	0	1.5	0	0.06
12.1	Fermented soybean products	0	0	0	0	2.5	2.5	0.02	0	0	0	0

* The applicant provided a range for the Normal use level instead of a single value, the highest figure in the range is here used.

Table 4 - **Upper Use Levels for all smoke flavourings under evaluation in each of the food products in the category "12. Salts, spices, soups, sauces, salads, protein products etc"**

12. Salts, spices, soups, sauces, salads, protein products etc.		Upper use level per APPLICATION (g/kg)										
		2	**4**	**6**	**7**	**8**	**9**	**10**	**13**	**14**	**15**	**16**
12.1	Salt and salt substitutes	0	0	0	0	0	0	0.03	0	0	3	0
12.2	Herbs, spices, seasonings and condiments	40	4	5	1	5	5	0.03	0	5	3	1
12.3	Vinegars	0	0	0	0	0	0	0.03	0	0	0	0
12.4	Mustards	0	0	0	0	0	0	0.03	0	0	0	0
12.5	Soups and broths	0	4	5	1	5	5	0.03	4	2	3	0.06
12.6	Sauces and like products	2	4	5	1	5	5	0.03	4	4	0	0.69
12.7.1	Salads (e.g. macaroni salad, potato salad)	0	0	0	0	5	5	0.03	0	0	0	0
12.7.2	Sandwich spreads excluding cocoa- and nut-based spreads	0	0	0	0	5	5	0.03	0	0	0	0.12
12.8	Yeast and like products	0	0	0	0	10	10	0.03	0	0	0	0
12.9	Protein products	0	0	0	0	10	10	0.03	0	3	0	0.24
12.1	Fermented soybean products	0	0	0	0	5	5	0.03	0	0	0	0

Table 5 - **Dietary exposure estimates calculated by means of the Maximised Survey-derived Daily Intake (MSDI) method**

	Europe[§]
Annual production (t)*	**10,000**
Annual production (kg) (1 t = 1,000 kg)	10,000,000
Survey response rate	0.60
Total population	320,000,000
Consumers (10%)	32,000,000
Number of days per year	365
MSDI (mg per capita/day)	1426.94
MSDI (mg per capita/day kg bw)	**23.8**

*SMK No 7 page 4: "In Europe the use has increased during the last 10 years and the market in Europe is estimated to be approx. 8-10,000 t liquid smoke and 2-3,000 t smoke powders and oils".

[§] It is here assumed that all the liquid smoke sold in Europe is produced by a unique company.

Table 6 - **Dietary exposure estimates calculated by means of the Single Portion Exposure Technique (SPET) and the Normal Use levels**

Groups		Products categories	Standard portions* (g/day)	SPET - Daily intake (mg/kg bw/day) per APPLICATION (Normal Use levels)										
				2	4	6	7	8	9	10	13	14	15	16
Traditionally smoked solid foods	1	Dairy products, …	40	0.0	0.0	3.3	0.3	1.7	1.7	0.0	0.0	1.0	1.7	0.0
	8	Meat and meat products, …	100	1.7	5.0	6.7	0.1	4.2	4.2	0.0	6.7	4.2	3.3	0.0
	9	Fish and fish products, …	100	1.7	5.0	6.7	0.1	4.2	4.2	0.0	0.0	2.5	3.3	0.0
Other solid foods not traditionally smoked	2	Fats and oils, …	15	0.3	0.0	0.0	0.0	0.6	0.6	0.0	0.0	0.0	0.4	0.0
	3	Edible ices, …	50	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	4.1	Processed fruits	125	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	3.1	0.0	0.0
	4.2	Processed vegetables …	200	0.0	10.0	16.7	1.7	4.0	4.0	0.0	0.0	5.0	0.0	0.0
	5	Confectionery	30	0.0	0.0	0.5	0.3	0.6	0.6	0.0	0.0	0.0	0.0	0.0
	6	Cereals and cereal products, …	200	0.0	0.0	0.0	0.0	4.0	4.0	0.0	0.0	0.0	5.0	0.0
	7	Bakery wares	80	0.0	0.0	1.3	0.7	3.3	3.3	0.0	0.0	0.0	2.0	0.0
	10	Eggs and egg products	100	0.0	0.0	0.0	0.0	2.0	2.0	0.0	0.0	0.0	0.0	0.0
	11	Sweeteners, including honey	30	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	12.1	Salt and salt substitutes	1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	12.2	Herbs, spices, …	1	0.3	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	12.3	Vinegars	15	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	12.4	Mustards	15	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	12.5	Soups and broths	200	0.0	6.7	3.3	0.0	8.3	8.3	0.1	10.0	3.3	8.3	0.0
	12.6	Sauces and like products	30	0.3	1.0	0.5	0.0	1.3	1.3	0.0	1.5	0.8	0.0	0.0
	12.7.1	Salads	120	0.0	0.0	0.0	0.0	5.0	5.0	0.0	0.0	0.0	0.0	0.0
	12.7.2	Sandwich spreads …	20	0.0	0.0	0.0	0.0	0.8	0.8	0.0	0.0	0.0	0.0	0.1
	12.8	Yeast and like products	5	0.0	0.0	0.0	0.0	0.4	0.4	0.0	0.0	0.0	0.0	0.0
	12.9	Protein products	15	0.0	0.0	0.0	0.0	1.3	1.3	0.0	0.0	0.4	0.0	0.0
	12.1	Fermented soybean products	40	0.0	0.0	0.0	0.0	1.7	1.7	0.0	0.0	0.0	0.0	0.0
	13	Foodstuffs intended for particular …	5	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	15	Ready-to-eat savouries	30	0.5	1.5	0.5	0.0	1.3	1.3	0.0	0.0	0.5	0.8	0.0
	16	Composite foods …	300	5.0	5.0	1.7	0.02	1.0	1.0	0.1	0.0	7.5	10.0	0.0
Beverages	14.1	Non-alcoholic ("soft") beverages, …	300	0.5	0.0	0.0	0.0	0.5	0.5	0.0	0.0	0.0	0.0	0.0
	14.2	Alcoholic beverages, …	300	0.5	5.0	5.0	0.5	0.3	0.3	0.0	0.0	0.0	12.5	0.0
Maximum intake				**5.0**	**10.0**	**16.7**	**1.7**	**8.3**	**8.3**	**0.1**	**10.0**	**7.5**	**12.5**	**0.1**

* Standard portion sizes based on those reported by: World Health Organisation (2009).

Table 7 - **Dietary exposure estimates calculated by means of the Single Portion Exposure Technique (SPET) and the Upper Use levels**

Groups		Products categories	Standard portions* (g/day)	SPET - Daily intake (mg/kg bw/day) per APPLICATION (Upper Use levels)										
				2	4	6	7	8	9	10	13	14	15	16
Traditionally smoked solid foods	1	Dairy products, …	40	0.0	0.0	3.3	0.3	3.3	3.3	0.0	0.0	2.7	2.0	0.0
	8	Meat and meat products, …	100	8.3	6.7	8.3	2.5	8.3	8.3	0.1	8.3	8.3	5.0	0.2
	9	Fish and fish products, …	100	8.3	6.7	8.3	2.5	8.3	8.3	0.1	0.0	8.3	5.0	0.0
Other solid foods not traditionally smoked	2	Fats and oils, …	15	0.3	0.0	0.0	0.0	1.3	1.3	0.0	0.0	0.0	0.8	0.0
	3	Edible ices, …	50	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	4.1	Processed fruits	125	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	10.4	0.0	0.0
	4.2	Processed vegetables …	200	0.0	10.0	16.7	1.7	8.3	8.3	0.0	0.0	16.7	0.0	0.0
	5	Confectionery	30	0.0	0.0	0.5	0.3	1.3	1.3	0.0	0.0	0.0	0.0	0.0
	6	Cereals and cereal products, …	200	0.0	0.0	0.0	0.0	8.3	8.3	0.0	0.0	0.0	10.0	0.0
	7	Bakery wares	80	0.0	0.0	1.3	0.7	6.7	6.7	0.0	0.0	0.0	4.0	0.0
	10	Eggs and egg products	100	0.0	0.0	0.0	0.0	4.2	4.2	0.0	0.0	0.0	0.0	0.0
	11	Sweeteners, including honey	30	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	12.1	Salt and salt substitutes	1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.0
	12.2	Herbs, spices, …	1	0.7	0.1	0.1	0.0	0.1	0.1	0.0	0.0	0.1	0.1	0.0
	12.3	Vinegars	15	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	12.4	Mustards	15	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	12.5	Soups and broths	200	0.0	13.3	16.7	3.3	16.7	16.7	0.1	13.3	6.7	10.0	0.2
	12.6	Sauces and like products	30	1.0	2.0	2.5	0.5	2.5	2.5	0.0	2.0	2.0	0.0	0.3
	12.7.1	Salads	120	0.0	0.0	0.0	0.0	10.0	10.0	0.1	0.0	0.0	0.0	0.0
	12.7.2	Sandwich spreads …	20	0.0	0.0	0.0	0.0	1.7	1.7	0.0	0.0	0.0	0.0	0.0
	12.8	Yeast and like products	5	0.0	0.0	0.0	0.0	0.8	0.8	0.0	0.0	0.0	0.0	0.0
	12.9	Protein products	15	0.0	0.0	0.0	0.0	2.5	2.5	0.0	0.0	0.8	0.0	0.1
	12.1	Fermented soybean products	40	0.0	0.0	0.0	0.0	3.3	3.3	0.0	0.0	0.0	0.0	0.0
	13	Foodstuffs intended for particular …	5	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	15	Ready-to-eat savouries	30	2.5	2.0	2.5	0.8	2.5	2.5	0.0	0.0	2.0	1.5	0.2
	16	Composite foods …	300	25.0	6.7	8.3	2.5	15.0	15.0	0.2	0.0	20.0	15.0	0.0
Beverages	14.1	Non-alcoholic ("soft") beverages, …	300	0.5	0.0	0.0	0.0	1.0	1.0	0.0	0.0	0.0	0.0	0.0
	14.2	Alcoholic beverages, …	300	0.5	5.0	5.0	0.5	0.5	0.5	0.0	0.0	0.0	15.0	0.0
Maximum intake				**25.0**	**13.3**	**16.7**	**3.3**	**16.7**	**16.7**	**0.2**	**13.3**	**20.0**	**15.0**	**0.3**

* Standard portion sizes based on those reported by: World Health Organisation (2009).

Table 8 - **Dietary exposure estimates calculated using the modified Theoretical Added Maximum Daily Intake (mTAMDI) method**

TAMDI products categories*	Portions (g/day)	mTAMDI - Daily intake (mg/kg bw/day) per APPLICATION (Normal Use levels)										
		2	**4**	**6**	**7**	**8**	**9**	**10**	**13**	**14**	**15**	**16**
Foods	133.4	2.2	6.7	11.1	1.1	5.6	5.6	0.0	8.9	5.6	5.6	0.0
Beverages (non-alcoholic)	324	0.5	0.0	0.0	0.0	0.5	0.5	0.0	0.0	0.0	0.0	0.0
Exception a: Candy, confectionery	27	0.0	0.0	0.5	0.2	0.5	0.5	0.0	0.0	0.0	0.0	0.0
Exception b: Condiments, seasonings	20	0.3	1.0	0.3	0.0	0.8	0.8	0.0	0.0	0.3	0.5	0.0
Exception c: Alcoholic beverages	20	0.0	0.3	0.3	0.0	0.0	0.0	0.0	0.0	0.0	0.8	0.0
Exception d: Soups, savouries	20	0.3	1.3	1.7	0.3	0.8	0.8	0.0	1.0	0.5	0.8	0.0
Exception e: Others, e.g. chewing gum	2	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total intake		**3.5**	**9.3**	**13.9**	**1.7**	**8.4**	**8.4**	**0.1**	**9.9**	**6.4**	**7.7**	**0.1**

* The seven food categories used in the TAMDI approach correspond to the 18 food categories as reported by the applicant in the way established by EFSA (2005).

Table 9 - **Dietary exposure estimates calculated using the Theoretical Added Maximum Daily Intake (TAMDI) method**

TAMDI products categories*	Portions (g/day)	TAMDI - Daily intake (mg/kg bw/day) per APPLICATION (Upper Use levels)										
		2	**4**	**6**	**7**	**8**	**9**	**10**	**13**	**14**	**15**	**16**
Foods	133.4	11.1	8.9	11.1	3.3	11.1	11.1	0.1	11.1	11.1	6.7	0.2
Beverages (non-alcoholic)	324	0.5	0.0	0.0	0.0	1.1	1.1	0.0	0.0	0.0	0.0	0.0
Exception a: Candy, confectionery	27	0.0	0.0	0.5	0.2	1.1	1.1	0.0	0.0	0.0	0.0	0.0
Exception b: Condiments, seasonings	20	1.7	1.3	1.7	0.5	1.7	1.7	0.0	0.0	1.3	1.0	0.2
Exception c: Alcoholic beverages	20	0.0	0.3	0.3	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0
Exception d: Soups, savouries	20	1.7	1.3	1.7	0.3	1.7	1.7	0.0	1.3	1.7	1.0	0.3
Exception e: Others, e.g. chewing gum	2	0.0	0.0	0.0	0.0	0.1	0.1	0.0	0.0	0.0	0.0	0.0
Total intake		**15.0**	**11.9**	**15.3**	**4.4**	**16.8**	**16.8**	**0.1**	**12.5**	**14.1**	**9.7**	**0.7**

* The seven food categories used in the TAMDI approach correspond to the 18 food categories as reported by the applicant in the way established by EFSA (2005).

Table 10 - **Dietary exposure estimates calculated using the Smoke Flavouring modified Theoretical Added Maximum Daily Intake (SMK-mTAMDI)**

Groups		Products categories	Standard portions* (g/day)	SMK mTAMDI - Daily intake (mg/kg bw/day) per APPLICATION (Normal Use levels)										
				2	**4**	**6**	**7**	**8**	**9**	**10**	**13**	**14**	**15**	**16**
Traditionally smoked solid foods	1	Dairy products, …	40	0.0	0.0	3.3	0.3	1.7	1.7	0.0	0.0	1.0	1.7	0.0
	8	Meat and meat products, …	100	1.7	5.0	6.7	0.1	4.2	4.2	0.0	6.7	4.2	3.3	0.0
	9	Fish and fish products, …	100	1.7	5.0	6.7	0.1	4.2	4.2	0.0	0.0	2.5	3.3	0.0
Other solid foods not traditionally smoked	2	Fats and oils, …	15	0.3	0.0	0.0	0.0	0.6	0.6	0.0	0.0	0.0	0.4	0.0
	3	Edible ices, …	50	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	4.1	Processed fruits	125	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	3.1	0.0	0.0
	4.2	Processed vegetables …	200	0.0	10.0	16.7	1.7	4.0	4.0	0.0	0.0	5.0	0.0	0.0
	5	Confectionery	30	0.0	0.0	0.5	0.3	0.6	0.6	0.0	0.0	0.0	0.0	0.0
	6	Cereals and cereal products, …	200	0.0	0.0	0.0	0.0	4.0	4.0	0.0	0.0	0.0	5.0	0.0
	7	Bakery wares	80	0.0	0.0	1.3	0.7	3.3	3.3	0.0	0.0	0.0	2.0	0.0
	10	Eggs and egg products	100	0.0	0.0	0.0	0.0	2.0	2.0	0.0	0.0	0.0	0.0	0.0
	11	Sweeteners, including honey	30	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	12.1	Salt and salt substitutes	1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	12.2	Herbs, spices, …	1	0.3	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	12.3	Vinegars	15	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	12.4	Mustards	15	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	12.5	Soups and broths	200	0.0	6.7	3.3	0.0	8.3	8.3	0.1	10.0	3.3	8.3	0.0
	12.6	Sauces and like products	30	0.3	1.0	0.5	0.0	1.3	1.3	0.0	1.5	0.8	0.0	0.0
	12.7.1	Salads	120	0.0	0.0	0.0	0.0	5.0	5.0	0.0	0.0	0.0	0.0	0.0
	12.7.2	Sandwich spreads …	20	0.0	0.0	0.0	0.0	0.8	0.8	0.0	0.0	0.0	0.0	0.1
	12.8	Yeast and like products	5	0.0	0.0	0.0	0.0	0.4	0.4	0.0	0.0	0.0	0.0	0.0
	12.9	Protein products	15	0.0	0.0	0.0	0.0	1.3	1.3	0.0	0.0	0.4	0.0	0.0
	12.1	Fermented soybean products	40	0.0	0.0	0.0	0.0	1.7	1.7	0.0	0.0	0.0	0.0	0.0
	13	Foodstuffs intended for particular …	5	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	15	Ready-to-eat savouries	30	0.5	1.5	0.5	0.0	1.3	1.3	0.0	0.0	0.5	0.8	0.0
	16	Composite foods …	300	5.0	5.0	1.7	0.02	1.0	1.0	0.1	0.0	7.5	10.0	0.0
Beverages	14.1	Non-alcoholic ("soft") beverages, …	300	0.5	0.0	0.0	0.0	0.5	0.5	0.0	0.0	0.0	0.0	0.0
	14.2	Alcoholic beverages, …	300	0.5	5.0	5.0	0.5	0.3	0.3	0.0	0.0	0.0	12.5	0.0
Maximum - Traditionally smoked food (meat, fish or cheese)				1.7	5.0	6.7	0.3	4.2	4.2	0.0	6.7	4.2	3.3	0.0
Maximum - Other foods not traditionally smoked				5.0	10.0	16.7	1.7	8.3	8.3	0.1	10.0	7.5	10.0	0.1
Maximum - Beverages (alcoholic or non-alcoholic)				0.5	5.0	5.0	0.5	0.5	0.5	0.0	0.0	0.0	12.5	0.0
Total maximum intake				**7.2**	**20.0**	**28.3**	**2.5**	**13.0**	**13.0**	**0.1**	**16.7**	**11.7**	**25.8**	**0.1**

* Standard portion sizes based on those reported by: World Health Organisation (2009).

Table 11 - **Dietary exposure estimates calculated using the Smoke Flavouring Theoretical Added Maximum Daily Intake (SMK-TAMDI)**

Groups		Products categories	Standard portions* (g/day)	SMK TAMDI - Daily intake (mg/kg bw/day) per APPLICATION (Upper Use levels)										
				2	4	6	7	8	9	10	13	14	15	16
Traditionally smoked solid foods	1	Dairy products, …	40	0.0	0.0	3.3	0.3	3.3	3.3	0.0	0.0	2.7	2.0	0.0
	8	Meat and meat products, …	100	8.3	6.7	8.3	2.5	8.3	8.3	0.1	8.3	8.3	5.0	0.2
	9	Fish and fish products, …	100	8.3	6.7	8.3	2.5	8.3	8.3	0.1	0.0	8.3	5.0	0.0
Other solid foods not traditionally smoked	2	Fats and oils, …	15	0.3	0.0	0.0	0.0	1.3	1.3	0.0	0.0	0.0	0.8	0.0
	3	Edible ices, …	50	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	4.1	Processed fruits	125	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	10.4	0.0	0.0
	4.2	Processed vegetables …	200	0.0	10.0	16.7	1.7	8.3	8.3	0.0	0.0	16.7	0.0	0.0
	5	Confectionery	30	0.0	0.0	0.5	0.3	1.3	1.3	0.0	0.0	0.0	0.0	0.0
	6	Cereals and cereal products, …	200	0.0	0.0	0.0	0.0	8.3	8.3	0.0	0.0	0.0	10.0	0.0
	7	Bakery wares	80	0.0	0.0	1.3	0.7	6.7	6.7	0.0	0.0	0.0	4.0	0.0
	10	Eggs and egg products	100	0.0	0.0	0.0	0.0	4.2	4.2	0.0	0.0	0.0	0.0	0.0
	11	Sweeteners, including honey	30	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	12.1	Salt and salt substitutes	1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.0
	12.2	Herbs, spices, …	1	0.7	0.1	0.1	0.0	0.1	0.1	0.0	0.0	0.1	0.1	0.0
	12.3	Vinegars	15	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	12.4	Mustards	15	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	12.5	Soups and broths	200	0.0	13.3	16.7	3.3	16.7	16.7	0.1	13.3	6.7	10.0	0.2
	12.6	Sauces and like products	30	1.0	2.0	2.5	0.5	2.5	2.5	0.0	2.0	2.0	0.0	0.3
	12.7.1	Salads	120	0.0	0.0	0.0	0.0	10.0	10.0	0.1	0.0	0.0	0.0	0.0
	12.7.2	Sandwich spreads …	20	0.0	0.0	0.0	0.0	1.7	1.7	0.0	0.0	0.0	0.0	0.0
	12.8	Yeast and like products	5	0.0	0.0	0.0	0.0	0.8	0.8	0.0	0.0	0.0	0.0	0.0
	12.9	Protein products	15	0.0	0.0	0.0	0.0	2.5	2.5	0.0	0.0	0.8	0.0	0.1
	12.1	Fermented soybean products	40	0.0	0.0	0.0	0.0	3.3	3.3	0.0	0.0	0.0	0.0	0.0
	13	Foodstuffs intended for particular …	5	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	15	Ready-to-eat savouries	30	2.5	2.0	2.5	0.8	2.5	2.5	0.0	0.0	2.0	1.5	0.2
	16	Composite foods …	300	25.0	6.7	8.3	2.5	15.0	15.0	0.2	0.0	20.0	15.0	0.0
Beverages	14.1	Non-alcoholic ("soft") beverages, …	300	0.5	0.0	0.0	0.0	1.0	1.0	0.0	0.0	0.0	0.0	0.0
	14.2	Alcoholic beverages, …	300	0.5	5.0	5.0	0.5	0.5	0.5	0.0	0.0	0.0	15.0	0.0
Maximum - Traditionally smoked food (meat, fish or cheese)				8.3	6.7	8.3	2.5	8.3	8.3	0.1	8.3	8.3	5.0	0.2
Maximum - Other foods not traditionally smoked				25.0	13.3	16.7	3.3	16.7	16.7	0.2	13.3	20.0	15.0	0.3
Maximum - Beverages (alcoholic or non-alcoholic)				0.5	5.0	5.0	0.5	1.0	1.0	0.0	0.0	0.0	15.0	0.0
Total maximum intake				**33.8**	**25.0**	**30.0**	**6.3**	**26.0**	**26.0**	**0.2**	**21.7**	**28.3**	**35.0**	**0.5**

* Standard portion sizes based on those reported by: World Health Organisation (2009).

Table 12 – **Consumption levels of Processed meat Fish and fish products and Cheese for males from different European Countries**

Men (Total population)		Number of subjects	Processed meat (g)		Smoked meat (g)			Smoked meat / Processed meat (%)	Fish and fish products (g)			Smoked fish and fish products[#] (g)		Cheese (g)			Smoked cheese[#] (g)	
			Mean*	SEM**	Mean*	SEM*	95th percentile[§]		Mean^	SEM^	95th percentile[§]	Estimated mean	95th percentile[§]	Mean°	SEM°	95th percentile[§]	Estimated mean	95th percentile[§]
Spain	Granada	243	48.3	4.7	1.1	2.9	-	2%	85.6	5.6	240	1.9	5.5	29.2	3.5	103	0.7	2.4
	Murcia	386	43.0	4.4	0.9	2.7	-	2%	65.1	5.3	220	1.4	4.6	18.8	3.3	73	0.4	1.5
	Navarra	444	51.5	3.2	6	2	-	12%	83.2	3.9	230	9.7	26.8	16.1	2.4	62	1.9	7.2
	San Sebastian	490	41.5	3.1	0	0	-	0%	120.1	3.8	278	0.0	0.0	23.9	2.4	88	0.0	0.0
	Asturias	214	54.6	3.5	6.6	2.2	-	12%	104.2	4.2	220	12.6	26.6	26	2.6	85	3.1	10.3
Italy	Ragusa	168	22.1	5.3	0	0	-	0%	28.2	6.4	108	0.0	0.0	52.9	4	146	0.0	0.0
	Florence	271	25.9	4.2	0.0	0.0	-	0%	37.0	5.0	136	0.0	0.0	39.9	3.1	124	0.0	0.0
	Turin	677	32.1	2.6	1.1	1.6	-	3%	34.4	3.2	129	1.2	4.4	47.8	2.0	138	1.6	4.7
	Varese	328	43.4	3.8	0.0	0.0	-	0%	19.7	4.5	76	0.0	0.0	45.5	3.1	139	0.0	0.0
United Kingdom	General population	404	41.1	3.4	19.5	2.1	72	47%	33.3	4.1	125	15.8	59.3	18.7	2.6	71	8.9	33.8
Germany	Heidelberg	1033	81.2	2.1	42.6	1.3	117	52%	16.9	2.6	65	8.9	33.9	48.3	1.6	138	25.3	72.6
	Potsdam	1235	88.5	1.9	51.9	1.2	130	59%	24.0	2.3	93	14.1	54.3	50.5	1.5	143	29.6	84.1
The Netherlands	Bilthoven	1024	70.3	2.2	38.5	1.4	115	55%	17.6	2.7	67	9.6	36.9	41.0	1.7	129	22.5	70.9
Sweden	Malmoe	1421	66.6	1.9	38.3	1.2	115	58%	41.9	2.3	152	24.1	87.5	38.9	1.4	124	22.4	71.3
	Umea	1344	67.9	1.9	44.3	1.2	123	65%	32.6	2.2	122	21.3	79.9	36.3	1.4	118	23.7	76.7

* Linseisen J, et al (2006); ** Linseisen J, et al (2002); ^ Welch AA et al. (2002); ° Hjartaker A *et al.* (2002)

[§] 95th percentile estimated by means of a lognormal distribution

[#] The average consumption of “Smoked fish and fish products” and "Smoked cheese" were calculated by assuming that the ratios between the average consumption of “Smoked fish and fish products” and “Fish and fish products” and between "Smoked cheese" and "Cheese" are equal to the ratio between the average consumption of "Smoked meat" and "Processed meat".

Table 13 **– Cumulative dietary exposure estimates for all the smoke flavourings under evaluation calculated using the Smoke Flavouring EPIC model (SMK-EPIC) and Normal Use Levels**

Groups		Products categories	Hypothesis	Food consumption (g/day)	EPIC model - Daily intake (mg/kg bw/day) per APPLICATION (Potsdam, Germany - Normal use levels)										
					2	**4**	**6**	**7**	**8**	**9**	**10**	**13**	**14**	**15**	**16**
Traditionally smoked solid foods	1	Dairy products, …	Average consumer	30	0.0	0.0	2.5	0.3	1.3	1.3	0.0	0.0	0.8	1.3	0.0
	8	Meat and meat products, …	High consumer	130	2.2	6.5	8.7	0.1	5.4	5.4	0.0	8.7	5.4	4.3	0.0
	9	Fish and fish products, …	Average consumer	14	0.2	0.7	0.9	0.0	0.6	0.6	0.0	0.0	0.4	0.5	0.0
Other solid foods not traditionally smoked	2	Fats and oils, …	1 portion* / week	2	0.0	0.0	0.0	0.0	0.1	0.1	0.0	0.0	0.0	0.1	0.0
	3	Edible ices, …	1 portion* / week	7	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	4.1	Processed fruits	1 portion* / week	18	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.4	0.0	0.0
	4.2	Processed vegetables …	1 portion* / week	29	0.0	1.4	2.4	0.2	0.6	0.6	0.0	0.0	0.7	0.0	0.0
	5	Confectionery	1 portion* / week	4	0.0	0.0	0.1	0.0	0.1	0.1	0.0	0.0	0.0	0.0	0.0
	6	Cereals and cereal products, …	1 portion* / week	29	0.0	0.0	0.0	0.0	0.6	0.6	0.0	0.0	0.0	0.7	0.0
	7	Bakery wares	1 portion* / week	11	0.0	0.0	0.2	0.1	0.5	0.5	0.0	0.0	0.0	0.3	0.0
	10	Eggs and egg products	1 portion* / week	14	0.0	0.0	0.0	0.0	0.3	0.3	0.0	0.0	0.0	0.0	0.0
	11	Sweeteners, including honey	1 portion* / week	4	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	12	Salts, spices, soups, sauces, …	1 portion* / week	4 - 29	0.0	1.0	0.5	0.0	1.2	1.2	0.0	1.4	0.5	1.2	0.0
	13	Foodstuffs intended for particular …	1 portion* / week	1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	15	Ready-to-eat savouries	1 portion* / week	4	0.1	0.2	0.1	0.0	0.2	0.2	0.0	0.0	0.1	0.1	0.0
	16	Composite foods …	1 portion* / week	43	0.7	0.7	0.2	0.002	0.1	0.1	0.0	0.0	1.1	1.4	0.0
Beverages	14	Non-alcoholic ("soft") beverages, …	1 portion* / week	43	0.1	0.0	0.0	0.0	0.1	0.1	0.0	0.0	0.0	0.0	0.0
	14	Alcoholic beverages, …	1 portion* / week	43	0.1	0.7	0.7	0.1	0.0	0.0	0.0	0.0	0.0	1.8	0.0
Total - Traditionally smoked food (meat, fish or cheese)					2.4	7.2	12.1	0.4	7.3	7.3	0.1	8.7	6.5	6.1	0.04
Total - Other foods not traditionally smoked					0.9	3.3	3.4	0.38	3.6	3.6	0.0	1.4	2.8	3.8	0.02
Total - Beverages (alcoholic or non-alcoholic)					0.1	0.7	0.7	0.1	0.1	0.1	0.0	0.0	0.0	1.8	0.00
Total intake					**3.4**	**11.2**	**16.2**	**0.8**	**10.9**	**10.9**	**0.1**	**10.1**	**9.3**	**11.6**	**0.06**

* Standard portion sizes based on those reported by: World Health Organisation (2009).

Table 14 **– Cumulative dietary exposure estimates for all the smoke flavourings under evaluation calculated using the Smoke Flavouring EPIC model (SMK-EPIC) and Upper Use Levels**

Groups		Products categories	Hypothesis	Food consumption (g/day)	EPIC model - Daily intake (mg/kg bw/day) per APPLICATION (Potsdam, Germany - Upper use levels)										
					2	**4**	**6**	**7**	**8**	**9**	**10**	**13**	**14**	**15**	**16**
Traditionally smoked solid foods	1	Dairy products, …	Average consumer	30	0.0	0.0	2.5	0.3	2.5	2.5	0.0	0.0	2.0	1.5	0.0
	8	Meat and meat products, …	High consumer	130	10.8	8.7	10.8	3.3	10.8	10.8	0.1	10.8	10.8	6.5	0.2
	9	Fish and fish products, …	Average consumer	14	1.2	0.9	1.2	0.4	1.2	1.2	0.0	0.0	1.2	0.7	0.0
Other solid foods not traditionally smoked	2	Fats and oils, …	1 portion* / week	2	0.0	0.0	0.0	0.0	0.2	0.2	0.0	0.0	0.0	0.1	0.0
	3	Edible ices, …	1 portion* / week	7	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	4.1	Processed fruits	1 portion* / week	18	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.5	0.0	0.0
	4.2	Processed vegetables …	1 portion* / week	29	0.0	1.4	2.4	0.2	1.2	1.2	0.0	0.0	2.4	0.0	0.0
	5	Confectionery	1 portion* / week	4	0.0	0.0	0.1	0.0	0.2	0.2	0.0	0.0	0.0	0.0	0.0
	6	Cereals and cereal products, …	1 portion* / week	29	0.0	0.0	0.0	0.0	1.2	1.2	0.0	0.0	0.0	1.4	0.0
	7	Bakery wares	1 portion* / week	11	0.0	0.0	0.2	0.1	1.0	1.0	0.0	0.0	0.0	0.6	0.0
	10	Eggs and egg products	1 portion* / week	14	0.0	0.0	0.0	0.0	0.6	0.6	0.0	0.0	0.0	0.0	0.0
	11	Sweeteners, including honey	1 portion* / week	4	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	12	Salts, spices, soups, sauces, …	1 portion* / week	4 - 29	0.1	1.9	2.4	0.5	2.4	2.4	0.0	1.9	1.0	1.4	0.0
	13	Foodstuffs intended for particular …	1 portion* / week	1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	15	Ready-to-eat savouries	1 portion* / week	4	0.4	0.3	0.4	0.1	0.4	0.4	0.0	0.0	0.3	0.2	0.0
	16	Composite foods …	1 portion* / week	43	3.6	1.0	1.2	0.4	2.1	2.1	0.0	0.0	2.9	2.1	0.0
Beverages	14	Non-alcoholic ("soft") beverages, …	1 portion* / week	43	0.1	0.0	0.0	0.0	0.1	0.1	0.0	0.0	0.0	0.0	0.0
	14	Alcoholic beverages, …	1 portion* / week	43	0.1	0.7	0.7	0.1	0.1	0.1	0.0	0.0	0.0	2.1	0.0
Total - Traditionally smoked food (meat, fish or cheese)					12.0	9.6	14.5	3.9	14.5	14.5	0.1	10.8	14.0	8.7	0.2
Total - Other foods not traditionally smoked					4.1	4.6	6.6	1.3	9.2	9.2	0.0	1.9	8.0	5.9	0.1
Total - Beverages (alcoholic or non-alcoholic)					0.1	0.7	0.7	0.1	0.2	0.2	0.0	0.0	0.0	2.1	0.0
Total intake					**16.3**	**14.9**	**21.8**	**5.2**	**23.9**	**23.9**	**0.1**	**12.7**	**22.0**	**16.7**	**0.3**

* Standard portion sizes based on those reported by: World Health Organisation (2009).

Table 15 - **Summary of the dietary exposure estimates calculated using the Normal Use Levels for all the smoke flavourings under evaluation**

Methodologies		**Summary - Daily intake (mg/kg bw/day) per method and APPLICATION** (Normal Use levels)										
		2	**4**	**6**	**7**	**8**	**9**	**10**	**13**	**14**	**15**	**16**
MSDI	*Europe*	**23.8**										
SPET	*Maximum intake*	**5.0**	**10.0**	**16.7**	**1.7**	**8.3**	**8.3**	**0.10**	**10.0**	**7.5**	**12.5**	**0.10**
mTAMDI	*Total maximum intake*	**3.5**	**9.3**	**13.9**	**1.7**	**8.4**	**8.4**	**0.06**	**9.9**	**6.4**	**7.7**	**0.07**
SMK-mTAMDI	Total - Traditionally smoked food	1.7	5.0	6.7	0.3	4.2	4.2	0.03	6.7	4.2	3.3	0.03
	Total - Other foods not traditionally smoked	5.0	10.0	16.7	1.7	8.3	8.3	0.10	10.0	7.5	10.0	0.10
	Total - Beverages (alcoholic or non-alcoholic)	0.5	5.0	5.0	0.5	0.5	0.5	0.00	0.0	0.0	12.5	0.00
	Total maximum intake	**7.2**	**20.0**	**28.3**	**2.5**	**13.0**	**13.0**	**0.13**	**16.7**	**11.7**	**25.8**	**0.13**
SMK-EPIC	Total - Traditionally smoked food	2.4	7.2	12.1	0.4	7.3	7.3	0.06	8.7	6.5	6.1	0.04
	Total - Other foods not traditionally smoked	0.9	3.3	3.4	0.4	3.6	3.6	0.02	1.4	2.8	3.8	0.02
	Total - Beverages (alcoholic or non-alcoholic)	0.1	0.7	0.7	0.1	0.1	0.1	0.00	0.0	0.0	1.8	0.00
	Total intake	**3.4**	**11.2**	**16.2**	**0.8**	**10.9**	**10.9**	**0.08**	**10.1**	**9.3**	**11.6**	**0.06**
Applicant	*Exposure estimate*	-	-	-	-	-	-	-	-	-	-	**0.08**

Table 16 - **Summary of the dietary exposure estimates calculated using the Upper Use Levels for all the smoke flavourings under evaluation**

Methodologies		**Summary - Daily intake (mg/kg bw/day) per method and APPLICATION** (Upper Use levels)										
		2	**4**	**6**	**7**	**8**	**9**	**10**	**13**	**14**	**15**	**16**
MSDI	*Europe*	**23.8**										
SPET	*Maximum intake*	**25.0**	**13.3**	**16.7**	**3.3**	**16.7**	**16.7**	**0.15**	**13.3**	**20.0**	**15.0**	**0.35**
TAMDI	*Total maximum intake*	**15.0**	**11.9**	**15.3**	**4.4**	**16.8**	**16.8**	**0.09**	**12.5**	**14.1**	**9.7**	**0.68**
SMK-TAMDI	Total - Traditionally smoked food	8.3	6.7	8.3	2.5	8.3	8.3	0.05	8.3	8.3	5.0	0.15
	Total - Other foods not traditionally smoked	25.0	13.3	16.7	3.3	16.7	16.7	0.15	13.3	20.0	15.0	0.35
	Total - Beverages (alcoholic or non-alcoholic)	0.5	5.0	5.0	0.5	1.0	1.0	0.00	0.0	0.0	15.0	0.00
	Total maximum intake	**33.8**	**25.0**	**30.0**	**6.3**	**26.0**	**26.0**	**0.20**	**21.7**	**28.3**	**35.0**	**0.50**
SMK-EPIC	Total - Traditionally smoked food	12.0	9.6	14.5	3.9	14.5	14.5	0.09	10.8	14.0	8.7	0.21
	Total - Other foods not traditionally smoked	4.1	4.6	6.6	1.3	9.2	9.2	0.04	1.9	8.0	5.9	0.08
	Total - Beverages (alcoholic or non-alcoholic)	0.1	0.7	0.7	0.1	0.2	0.2	0.00	0.0	0.0	2.1	0.00
	Total intake	**16.3**	**14.9**	**21.8**	**5.2**	**23.9**	**23.9**	**0.13**	**12.7**	**22.0**	**16.7**	**0.29**
Applicant	*Exposure estimate*	**-**	**5.9**	**14.0**	**2.6**	**-**	**-**	**-**	**17.0**	**30.0**	**-**	**-**

ANNEX 2

Applications SMK No	Name of the Primary Product	Name of the Applicant
2	Sofral primary beech smoke condensate	Sofral
4	Scansmoke PB R909	proFagus GmbH
6	Scansmoke PB 1110	Brøste A/S
7	Scansmoke SEF 7525	Brøste A/S
8	SmokeEz C-10/CharSol Sol C-10	Red Arrow Products Company LLC
9	SmokeEz Enviro 23/CharSol Select 23	Red Arrow Products Company LLC
10	Fumokomp	KOMPOZÍCIÓ KFT.,
13	Unismoke	Unilever Foods Netherlands
14	Zesti Smoke Code 10/ Zesti Hickory smoke Code 10	Mastertaste
15	AM 01	Aromarco s.r.o.
16	Smoke Concentrate 809045	Symrise GmbH & Co. KG