

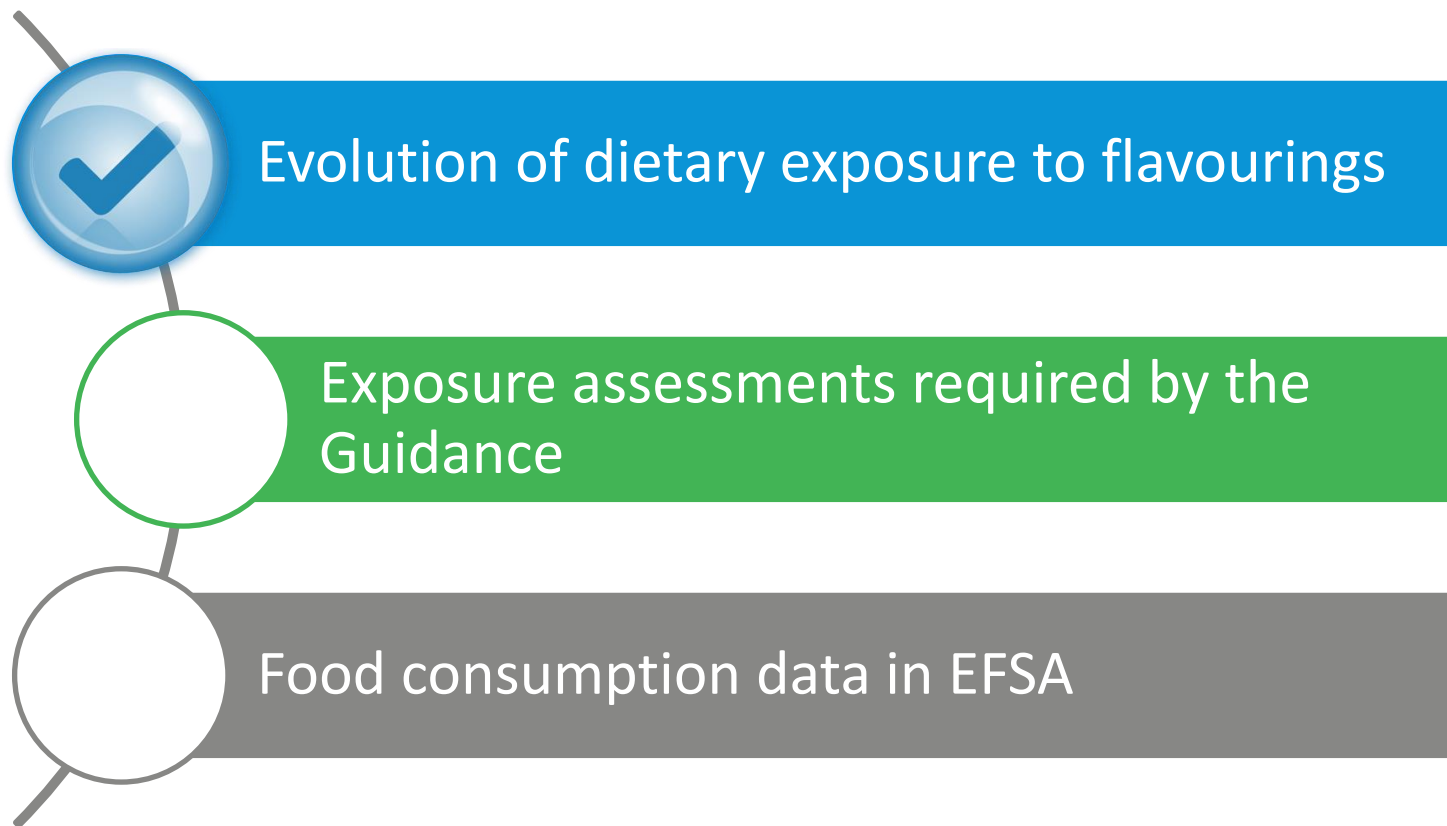


Exposure Assessment to food flavouring substances


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Technical meeting on food flavourings applications
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SUMMARY



EVOLUTION OF DIETARY EXPOSURE TO FLAVOURINGS

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- 2000** The European Commission adopted the approach developed by JECFA for the risk assessment of flavourings to be used in or on foods, exposure is estimated by means of the “Maximised Survey-derived Daily Intake” (MSDI) method.
- 2005** The “modified Theoretical Added Maximum Daily Intake” (mTAMDI) is added to the EFSA procedure to screen and prioritise the flavouring substances according to the need for refined intake data.
- 2008** JECFA develops the “Single Portion Exposure Technique” (SPET), a complementary method to assess dietary exposure to flavouring substances.
- 2010** EFSA requires the use of the “Added Portions Exposure Technique” (APET) in its Guidance.

MAXIMISED SURVEY-DERIVED DAILY INTAKE (MSDI)

Maximised Survey-derived Daily Intake

(MSDI) =

Annual production (kg) $\times 10^9$ ($\mu\text{g}/\text{kg}$)

Consumers \times **survey response rate** $\times 365$ (days)

Annual production volume in one year in Europe

Consumers: estimated to be 10% of the total European population (= 32,000,000)

Survey response rate: correction made to take into account that survey data provided by industry could be incomplete (= 0.6 in Europe)



EXAMPLE

Pentyl isovalerate

Production volume of in Europe in 1995: 77 kg

$$\text{MSDI: } \frac{77 \times 10^9}{32,000,000 \times 0.6 \times 365} = 11 \mu\text{g /day}$$

USAGE LEVELS

In order to enable the evaluation of a substance, the **EC Regulation requires** that the person responsible for placing on the market a flavouring substance has to provide **normal** and **upper use levels** of the substances according to specific food categories, if available.

1. Dairy products, excluding products of category 2.
2. Fats and oils, and fat emulsions (type water-in-oil).
3. Edible ices, including sherbet and sorbet.
4. Processed fruits and vegetables, and nuts and seeds.
 - 4.1 Fruit.
 - 4.2 Vegetables, and nuts and seeds.
5. Confectionery.
6. Cereals and cereal products, including flours and starches from roots and tubers, pulses and legumes, excluding bakery.
7. Bakery wares.
8. Meat and meat products, including poultry and game.
9. Fish and fish products, including molluscs, crustaceans and echinoderms (MCE).
10. Eggs and egg products.
11. Sweeteners, including honey.
12. Salts, spices, soups, sauces, salads, protein products, etc.
13. Foodstuffs intended for particular nutritional uses.
14. Beverages, excluding dairy products.
 - 14.1 Non-alcoholic ('soft') beverages.
 - 14.2 Alcoholic beverages, including alcohol-free and low-alcoholic counterparts.
15. Ready-to-eat savouries.
16. Composite foods (e.g. casseroles, meat pies, mincemeat), foods that could not be placed in categories 1 to 15.

THEORETICAL ADDED MAXIMUM DAILY INTAKE (TAMDI)

The TAMDI method (Cadby, 1996) assumes that:

- the hypothetical consumer will day in day out consume a fixed amount (standard portions) of flavoured food and beverages and
- that these items will always contain the specific flavouring at its specified Upper Use Level.

Cadby, P. (1996) Estimating intakes of flavouring substances. Food Additives and Contaminants, 13, (4) 453-60.

TAMDI BASIC ASSUMPTIONS




Foods and beverages	Consumption (g/day)	Content (mg/day)
Beverages (not alcoholic)	324	Upper Use Level
Foods	133	Upper Use Level
Exceptions:		
Candy, confectionery	27	Upper Use Level
Condiments, seasonings	20	Upper Use Level
Alcoholic beverages	20	Upper Use Level
Soups, savouries	20	Upper Use Level
Other exceptions (e.g. chewing gums)	2	Upper Use Level

TAMDI - EXAMPLE

Foods and beverages	Consumption (g/day)	Upper Use Level (mg/kg)	Estimated intake (mg/day)
Beverages (not alcoholic)	324	0	0.000
Foods	133	3.5	0.465
Exceptions:			
Candy, confectionery	27	0	0.000
Condiments, seasonings	20	2.75	0.055
Alcoholic beverages	20	0.1	0.002
Soups, savouries	20	1	0.020
Chewing gums	2	0	0.000
Total			0.542

MODIFIED TAMDI (MTAMDI)



Foods and beverages	Consumption (g/day)	Content (mg/day)
Beverages (not alcoholic)	324	Normal Use Level
Foods	133	Normal Use Level
Exceptions:		
Candy, confectionery	27	Normal Use Level
Condiments, seasonings	20	Normal Use Level
Alcoholic beverages	20	Normal Use Level
Soups, savouries	20	Normal Use Level
Other exceptions (e.g. chewing gums)	2	Normal Use Level

The mTAMDI was used by the AFC/CEF Panel to screen and prioritise the flavouring substances according to the need for refined intake data.

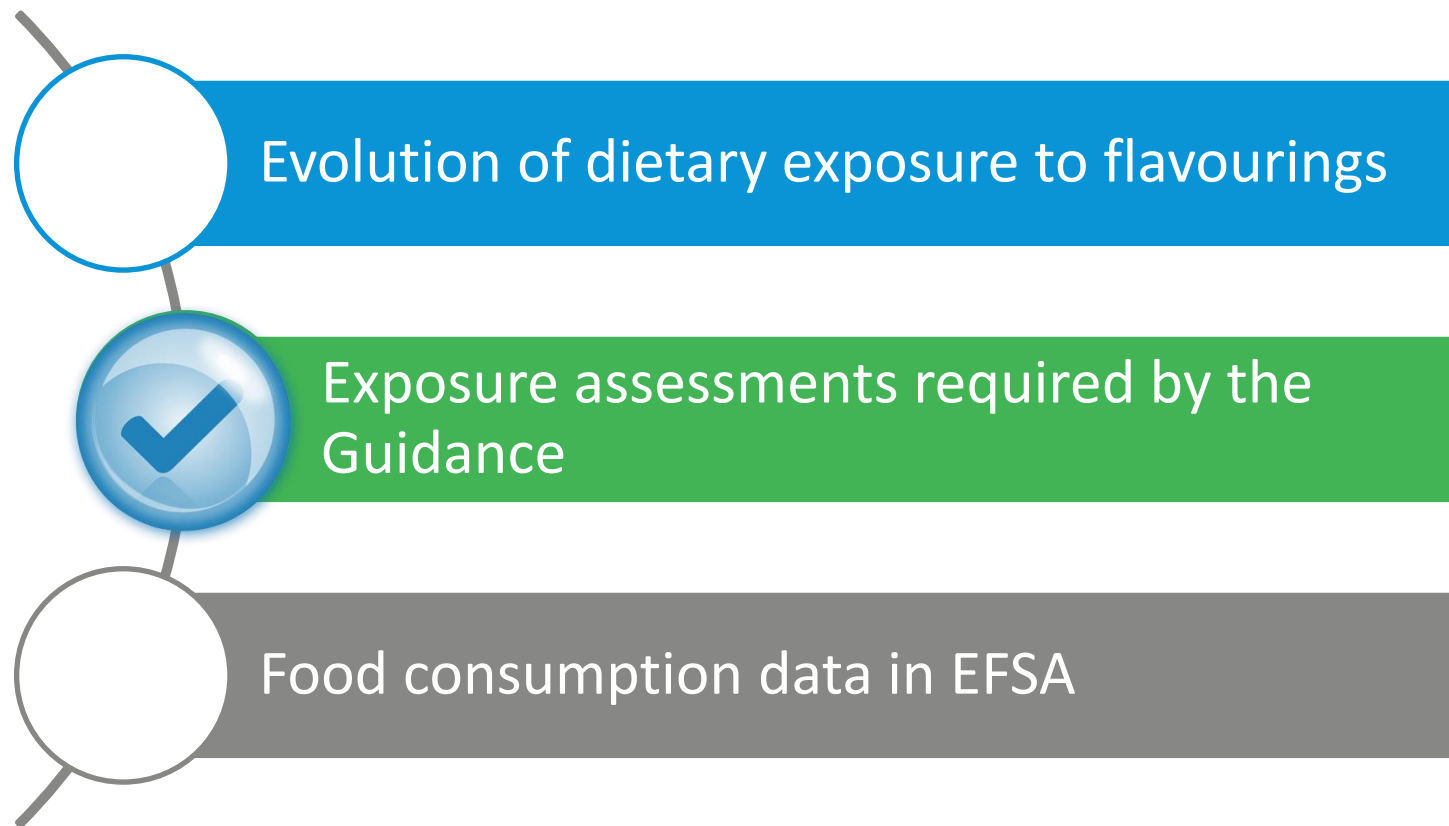
SINGLE PORTION EXPOSURE TECHNIQUE (SPET)

The SPET assumes that a regular consumer of a flavoured food is loyal to a specific product containing the specific flavouring of interest.

The SPET is based on:

- **Food categories:** from the Codex General Standard for Food Additives (GSFA)
- **Portion sizes** based on large part on regulatory United States standard portion sizes
- **Body weight:** standard at 60 kg
- **Added use levels:** average (or usual)
- **In case of multiple food categories:** only the food category resulting in the highest potential dietary exposure is considered.

SUMMARY



ADDED PORTIONS EXPOSURE TECHNIQUE (APET)

The APET assumes that a regular consumer is loyal to a specific solid food and a specific beverage, both containing the flavouring of interest.

The APET is based on:

- **Food categories:** from the Codex General Standard for Food Additives (GSFA)
- **Portion sizes** based on large part on regulatory United States standard portion sizes
- **Body weight:** standard at 60 kg
- **Added use levels:** average (or usual)
- **In case of multiple food categories:** the highest potential dietary exposure within each of the two groups ("Beverages" and "Solid foods") is considered and summed up.

3 YEARS CHILDREN EXPOSURE

A child of 3 years of age is considered as a conservative scenario for all children aged more than 3.

The APET is calculated by means of:

- **Food categories:** from the Codex General Standard for Food Additives (GSFA).
 - Children are supposed not to consume “Alcoholic beverages” and “Dietetic formulae for slimming purposes and weight reduction”
- **Portion sizes:** obtained by multiplying the adult standard portion sizes by a factor of 0.63.
 - The correction factor has been calculated based on the lower energy requirement of children with respect to adults.
- **Body weight:** standard at 15kg
- **Added use levels:** average (or usual)
- **In case of multiple food categories:** the highest potential dietary exposure within “Beverages” and “Solid foods” are considered and summed up.


INFANTS AND YOUNG CHILDREN EXPOSURE

A specific exposure assessment model diet is provided for a 12-month young child fed milk and a variety of processed baby foods flavoured with the substance of interest.

The exposure model is based on:

- **Food categories:** specifically designed for these consumer subgroups
- **Portion sizes:** based on large part on regulatory United States standard portion sizes specific for these population groups
- **Body weight:** standard at 10 kg
- **Added use levels:** Maximum (or upper)
- **In case of multiple food categories:** potential dietary exposure from all foods and beverage categories specifically designed for these consumer subgroups are considered and summed up.

ACUTE DIETARY EXPOSURE



In case the estimated level of dietary exposure may raise any concern about acute adverse effects of a flavouring substance, acute exposure should be assessed for adults and children with the APET method based on:

- **Food categories:** from the Codex General Standard for Food Additives (GSFA)
- **Portion sizes** based on large part on regulatory United States standard portion sizes multiplied by 3
- **Body weight:** standard at 60 kg
- **Added use levels:** maximum (or usual)
- **In case of multiple food categories:** the highest potential dietary exposure within each of the two groups ("Beverages" and "Solid foods") is considered and summed up.

NATURAL OCCURRENCE OF FLAVOURING SUBSTANCES

Flavouring substances might also be naturally present in foods or beverages.

Information about the levels of flavouring substances

- as **natural constituent** and/or
 - developed during the normal **processing** of foods
- are supposed to be provided by the applicant if this information is available in the literature or in ad hoc databases.

In this cases dietary exposure must be calculated based on:

1. occurrence levels from **added flavourings**
2. occurrence levels from **other dietary sources**
3. **combined occurrence levels.**

CUMULATIVE DIETARY EXPOSURE

Potential cumulative dietary exposure must be estimated based on occurrence levels for the new substance but also for structurally and metabolically related substances.

The applicant shall:

- retrieve the most recent **EU poundage data** for all flavouring substances structurally and metabolically related to the new substance
- retrieve **normal occurrence levels** for the **five substances with the highest poundage**
- Use the **APET** (adults and children) and the **ad hoc model for infants and young children** to assess exposure to the top five substances
- Potential cumulative dietary exposure is estimated by **summing up the exposure to the top five substances**

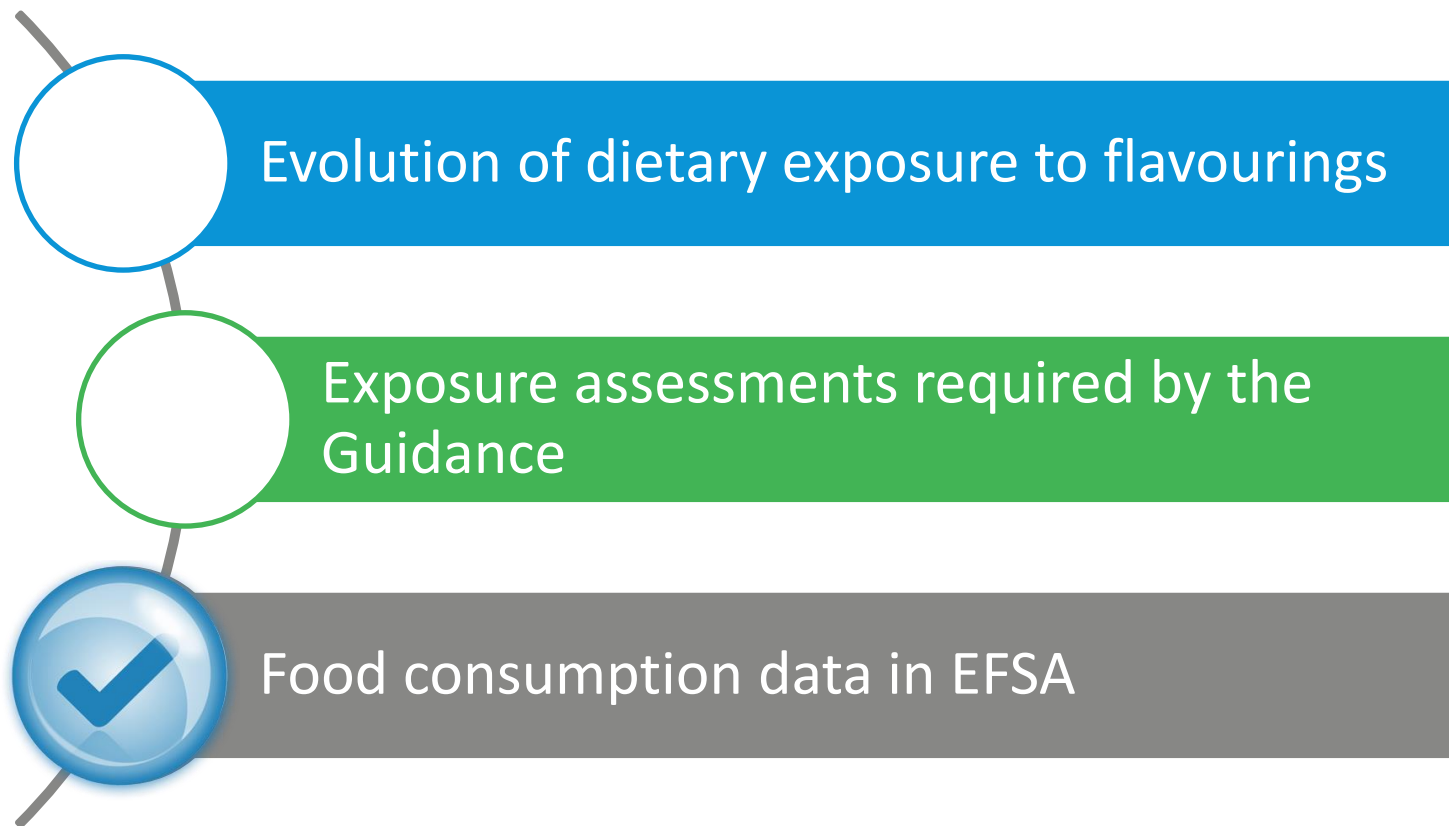
NON-FOOD USES OF THE FLAVOURING SUBSTANCE

In order to identify non-food sources of exposure, applicants should provide information on:

- the **non-food uses** of the flavouring substance (e.g. in cosmetics, medicines and detergents)
- **content** of the substance in these products, and
- its **absorption rates** via skin and/or inhalation.



SUMMARY



CONSUMPTION DATA

The EFSA Comprehensive European food consumption database contains data:

- 24-hour recall or dietary record method
- data collected at individual level
- most recent data within each country
- random sample at national level
 - different age classes, from infants to elderly
 - special population groups



MAGNITUDE OF THE CONSUMPTION DATABASE

Number of

Member States	23
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Dietary surveys	49
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Population groups	107
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Subjects	93,570
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Different national food codes	125,531
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Different standard food codes	1,787
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Consumption records	10,426,602
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EFSA DIETARY SURVEY GUIDELINE



EFSA Journal 2014;12(12):3944

GUIDANCE OF EFSA

Guidance on the EU Menu methodology¹

European Food Safety Authority^{2,3}

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

The availability of detailed, harmonised and high-quality food consumption data for use in dietary exposure assessments is a long-term objective of EFSA. In 2009, the EFSA guidance on “General principles for the collection of national food consumption data in the view of a pan-European dietary survey” was published, and a pan-European food consumption survey, also known as the “EU Menu”, was launched. Based on the 2009 EFSA guidance, two EU Menu feasibility pilot studies and two methodological projects, EFSA has updated the former guidance document to cover the EU Menu methodology and therefore facilitate the collection of more harmonised food consumption data from all European Union Member States by the year 2020. This guidance has been developed by the EFSA Evidence Management Unit (DATA) and the EU Menu Working Group with Advisory Function, and has been endorsed by the EFSA Network on Food Consumption Data. It provides recommendations for the collection of more harmonised food consumption data among the EU Member States for use in dietary exposure assessments of food-borne hazards and nutrient intake estimations under the remit of EFSA’s scientific panels. Food consumption information should be collected for two non-consecutive days. The 24-hour food diary method, followed by a computer-assisted personal or telephone interview (CAPI/CATI), should be used to collect data from infants and children. For all other age groups, the 24-hour dietary recall CAPI/CATI method should be used. The reported foods should be described in accordance with the EFSA FoodEx2 food classification system. A short food propensity questionnaire should be used to collect information on the consumption of some less frequently eaten foods and the consumption frequencies of food supplements. Information on the weight, height and physical activity levels of participants should also be collected in the survey.

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KEY WORDS

EU Menu, pan-European dietary survey, food consumption, exposure assessment, 24-hour recall, food diary, harmonisation

European Food Safety Authority, 2014. Guidance on the EU Menu methodology.
EFSA Journal 2014;12(12):3944, 77 pp. doi:10.2903/j.efsa.2014.3944



Thank you!



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