Exposure Assessment to food flavouring substances

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Evolution of dietary exposure to flavourings
Exposure assessments required by the Guidance
Food consumption data in EFSA
EVOLUTION OF DIETARY EXPOSURE TO FLAVOURINGS

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) =

\[ \text{Annual production (kg)} \times 10^9 (\mu g/kg) \times \text{Consumers} \times \text{survey response rate} \times 365 \text{ (days)} \]

**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

MSDI: \[
\frac{77 \times 10^9}{32,000,000 \times 0.6 \times 365} = 11 \ \text{μg /day}
\]
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.
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.
   14.1 Non-alcoholic (‘soft’) beverages.
   14.2 Alcoholic beverages, including alcohol-free and low-alcoholic counterparts.
16. Composite foods (e.g. casseroles, meat pies, mincemeat), foods that could not be placed in categories 1 to 15.
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.
## TAMDI BASIC ASSUMPTIONS

<table>
<thead>
<tr>
<th>Foods and beverages</th>
<th>Consumption (g/day)</th>
<th>Content (mg/day)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beverages (not alcoholic)</td>
<td>324</td>
<td>Upper Use Level</td>
</tr>
<tr>
<td>Foods</td>
<td>133</td>
<td>Upper Use Level</td>
</tr>
<tr>
<td>Exceptions:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Candy, confectionery</td>
<td>27</td>
<td>Upper Use Level</td>
</tr>
<tr>
<td>Condiments, seasonings</td>
<td>20</td>
<td>Upper Use Level</td>
</tr>
<tr>
<td>Alcoholic beverages</td>
<td>20</td>
<td>Upper Use Level</td>
</tr>
<tr>
<td>Soups, savouries</td>
<td>20</td>
<td>Upper Use Level</td>
</tr>
<tr>
<td>Other exceptions (e.g. chewing gums)</td>
<td>2</td>
<td>Upper Use Level</td>
</tr>
<tr>
<td>Foods and beverages</td>
<td>Consumption (g/day)</td>
<td>Upper Use Level (mg/kg)</td>
</tr>
<tr>
<td>--------------------------------------</td>
<td>---------------------</td>
<td>-------------------------</td>
</tr>
<tr>
<td>Beverages (not alcoholic)</td>
<td>324</td>
<td>0</td>
</tr>
<tr>
<td>Foods</td>
<td>133</td>
<td>3.5</td>
</tr>
<tr>
<td>Exceptions:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Candy, confectionery</td>
<td>27</td>
<td>0</td>
</tr>
<tr>
<td>Condiments, seasonings</td>
<td>20</td>
<td>2.75</td>
</tr>
<tr>
<td>Alcoholic beverages</td>
<td>20</td>
<td>0.1</td>
</tr>
<tr>
<td>Soups, savouries</td>
<td>20</td>
<td>1</td>
</tr>
<tr>
<td>Chewing gums</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>542</strong></td>
<td></td>
</tr>
</tbody>
</table>
MODIFIED TAMDI (MTAMDI)

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

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

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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.
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
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.
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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

<table>
<thead>
<tr>
<th>Number of</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Member States</td>
<td>23</td>
</tr>
<tr>
<td>Dietary surveys</td>
<td>49</td>
</tr>
<tr>
<td>Population groups</td>
<td>107</td>
</tr>
<tr>
<td>Subjects</td>
<td>93,570</td>
</tr>
<tr>
<td>Different national food codes</td>
<td>125,531</td>
</tr>
<tr>
<td>Different standard food codes</td>
<td>1,787</td>
</tr>
<tr>
<td>Consumption records</td>
<td>10,426,602</td>
</tr>
</tbody>
</table>
GUIDANCE OF EFSA

Guidance on the EU Menu methodology

European Food Safety Authority

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

Thank you!

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