Flavourings – Legislation and Safety Assessment

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Food Improvement Agents Package (FIAP)

- Regulation 1331/2008 establishing a common authorisation procedure for additives, enzymes and flavourings

- Regulation 1332/2008 on food enzymes

- Regulation 1333/2008 on food additives

- Regulation 1334/2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods
Currently applicable EU legislation on flavourings

<table>
<thead>
<tr>
<th>Legislative Instrument</th>
<th>Content of the legislation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulation 1331/2008</td>
<td>establishes a common procedure for the authorisation (by the European Commission) for food additives, food enzymes and food flavourings, before they can be used in food</td>
</tr>
<tr>
<td>Regulation 1334/2008</td>
<td>lays down the legislative requirements for flavourings and certain food ingredients with flavouring properties for use in and on foods</td>
</tr>
<tr>
<td>Regulation 234/2011</td>
<td>lays down the specific data that are required for the risk assessment and risk management of flavourings</td>
</tr>
<tr>
<td>Regulation 872/2012</td>
<td>adopts the list of flavouring substances (Annex I, Part A, to Regulation 1334/2008.)</td>
</tr>
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<tr>
<td>Commission Decision 1999/217/EC</td>
<td>gave force to a Community register of flavouring substances that can be used in or on foodstuffs until date of application of list of chemically defined flavouring substances (22 April 2013). <em>Repealed as of that date</em></td>
</tr>
<tr>
<td>Regulation 873/2012</td>
<td>provides transitional measures concerning the Union list of flavourings and source materials</td>
</tr>
<tr>
<td>Regulation 2065/2003 on smoke flavourings</td>
<td>lays down the procedure for regulation and evaluation of the “primary products” which are the main ingredients in smoke flavourings, while the associated Regulation 627/2006 lays down quality criteria for analytical methods for sampling, identification and characterisation of these products</td>
</tr>
</tbody>
</table>
Regulation 1334/2008

- Entered into force 20\textsuperscript{th} January 2009
- Most articles applied from 20\textsuperscript{th} January 2011
- Sections relating to the Union list apply from 22 April 2013
- Core principles and provisions of the previous legislation (Regs. 88/388 and 91/171) are maintained
Core principles and provisions

- definition of flavourings
- general rules for their use
- designation of flavourings in list of ingredients
- requirements for labelling
- maximum levels for substances which raise concern for human health

New aspects include:

- adoption and updating of Union list of flavourings through comitology
- Core role for EFSA in the risk assessment of flavourings
What is a flavouring?

Defined in Art 3.2.(a)

- Not consumed as such, added to impart or modify odour and/or taste

- Consists of one or more of the 6 flavour categories:
  - Flavouring preparations, flavouring substances, smoke flavourings, thermal process flavourings, flavour precursors and other flavourings

- Can also contain additives and food ingredients
What is a flavouring?

- a single flavouring substance, e.g. vanillin

- Mixture of flavouring components
  - typically contains 30/40 substances
  - flavour components - very low levels and the flavouring used also at very low levels.
  - also non flavouring materials e.g. solvents, antioxidants and emulsifiers
Flavouring substance versus flavouring preparation?

- A **flavouring substance** is a defined chemical substance, e.g. Menthol.

- A **flavouring preparation** is not a defined chemical substance, e.g. peppermint oil.
PEPPERMINT FLAVOURING

<table>
<thead>
<tr>
<th>Component</th>
<th>Concentration (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peppermint oil</td>
<td>2.5</td>
</tr>
<tr>
<td>Water</td>
<td>77.5</td>
</tr>
<tr>
<td>Alcohol (ethyl alcohol)</td>
<td>20.0</td>
</tr>
</tbody>
</table>

% content of main flavouring substances in the peppermint oil (2.5%)

- Menthol                          | 0.75 – 1.38       |
- Menthone                          | 0.35 – 0.80       |
- Menthone                          | 0.35 – 0.80       |
- Menthyl acetate                   | 0.07 – 0.25       |
- Isomenthone                       | 0.04 – 0.25       |
- Menthofuran                       | 0.025 – 0.23      |
- Cineole                           | 0.09 – 0.35       |
- Pulegone                          | < 0.1             |
- Carvone                           | < 0.025           |
- Isopulegol                        | < 0.005           |
- α-pinene, β-pinene                | < 0.001           |

Etc.
Types of flavourings

Flavouring substances

Flavouring preparations
- from sources other than food

Flavour precursors
- from sources other than food

Smoke flavourings

“Union list”

Thermal process flavour
- from sources other than food and/or > 180°C

Source materials
- from sources other than food

Other flavourings
Examples of the various flavouring categories

- **Natural flavouring substance:**
  - Limonene obtained from oranges

- **Flavouring substance:**
  - Ethyl butyrate made by a chemical route

- **Flavouring preparation:**
  - Orange oil

- **Thermal process flavouring:**
  - A meat flavour made by heating xylose (a reducing sugar) and cysteine (an amino acid)

- **Precursor flavouring:**
  - An unheated blend of amino acids and sugars which will produce a flavour in the final food

- **Other flavouring**
  - It’s there just in case!
Labelling provisions in 1334/2008 are more rigorous than before

- Articles 14-16 cover general labelling provisions for business to business labelling.

- Article 17 covers sales of flavourings direct to the consumer (e.g. small bottles used for home baking).

- Article 29 covers the designation of flavourings in the ingredient list of the final food but makes reference to Article 16 (provisions regarding the use of the word “natural”).
Ingredient list designation (labelling) under 1334/2008

- Specifies when “natural flavouring” can be used to describe a flavouring in the ingredient list.

- Can’t just say “natural flavouring” in most cases.

- Flavouring preparations and natural flavouring substances can be used in natural flavourings – the other categories of flavouring materials cannot be present.

- The presence of other non-natural materials, e.g. solvents, does not affect the natural status.
MORE FROM ANNE-MARIE!
Presence of certain undesirable substances

- Some food/flavour extracts naturally contain low levels of substances which are thought to have toxicological issues. E.g. menthofuran

- These substances can’t be added as such.

- Majority of the materials were restricted in the previous legislation but the way this is done has been changed in Regulation 1334/2008
Active principles

Allowed at any level in foods apart from those listed where a maximum level is set

Maximum level set in all food with higher levels for certain specialist categories.

NEW

OLD
Presence of certain undesirable substances

- Regulation 1334/2008 only controls those sources that have a key influence on intake.

- There is no overall level set in food.

- There are specific levels for those foods which are thought to provide the major intake.

- The principles of general food law apply.
### Examples of restrictions

<table>
<thead>
<tr>
<th>Substance</th>
<th>Food</th>
<th>Max. level</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>mg/kg or mg/l</td>
</tr>
<tr>
<td>Estragol</td>
<td>Dairy products, Processed fruits</td>
<td>50</td>
</tr>
<tr>
<td></td>
<td>vegetables, nuts and seeds</td>
<td>50</td>
</tr>
<tr>
<td></td>
<td>Fish products</td>
<td>50</td>
</tr>
<tr>
<td></td>
<td>Non-alcoholic beverages</td>
<td>10</td>
</tr>
<tr>
<td>Hydrocyanic acid</td>
<td>Nougat, marzipan or its substitutes or similar products</td>
<td>50</td>
</tr>
<tr>
<td></td>
<td>Canned stone fruits</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Alcoholic beverages</td>
<td>35</td>
</tr>
<tr>
<td>Menthofuran</td>
<td>Mint/peppermint-containing confectionery, except .....</td>
<td>500</td>
</tr>
<tr>
<td></td>
<td>Micro breath freshening</td>
<td></td>
</tr>
<tr>
<td></td>
<td>confectionery</td>
<td>3000</td>
</tr>
<tr>
<td></td>
<td>Chewing gum</td>
<td>1000</td>
</tr>
<tr>
<td></td>
<td>Mint/peppermint containing alcoholic beverages</td>
<td>200</td>
</tr>
</tbody>
</table>
The Community Register of flavouring substances

Commission Decision 88/379/EC
- established an inventory of source materials and substances used in the preparation of flavourings
- forerunner to the register of flavouring substances

Com. Decision 1999/217/EC
- register of approximately 2600 flavouring substances in use in food in the EU
- evaluation programme
The Community Register of flavouring substances 2002-2012

- **2067** SUBSTANCES EVALUATED BY EFSA:

- **570** SUBSTANCES EVALUATED BEFORE EFSA:

- **+ 21** SUBSTANCES DELETED FROM REGISTER on request of industry

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- **2658** SUBSTANCES IN EFSA FLAVIS DATABASE (Register + New substances)
EU list of flavouring substances

COMMISSION IMPLEMENTING REGULATION (EU) No 872/2012


- Adopted by qualified majority at SCOFAH, 23 April, 2012, final adoption/publication 1 October 2012.
Transitional measures

COMMISSION REGULATION (EU) No 873/2012 on transitional measures concerning the Union list of flavourings and source materials set out in Annex I of Regulation (EC) No 1334/2008

- adoption of the Annex could have meant that all substances/ processes etc. not included in the Annex should be prohibited from 6 months after adoption

- But not yet evaluated!

- Regulation 873/2012 allows transitional measures while evaluation is completed
<table>
<thead>
<tr>
<th>Date</th>
<th>Applicable provision</th>
</tr>
</thead>
<tbody>
<tr>
<td>22 April, 2013</td>
<td>Union list of flavouring substances applies</td>
</tr>
<tr>
<td>31 Dec. 2013</td>
<td>Latest date for submission of data requested by EFSA on “footnote (1)” flavouring substances</td>
</tr>
<tr>
<td>22 Oct. 2014</td>
<td>Food containing flavouring substances not included in the Union list may be only be marketed until date of minimum durability or ‘use-by’ date is reached</td>
</tr>
<tr>
<td>22 Oct. 2015</td>
<td>Deadline for submission of application by industry for authorisation of a flavouring preparation, thermal process flavouring, flavour precursor, other flavouring or source material</td>
</tr>
<tr>
<td>22 Oct. 2016</td>
<td>Parts B to F of Annex 1 of Regulation 1334/2008 apply. Foods containing flavourings and source materials which do not comply with parts B to F of Annex 1 may be only be marketed until their date of minimum durability or ‘use-by’ date is reached</td>
</tr>
</tbody>
</table>
Safety assessment of flavourings in the EC

- Large number of flavourings and flavouring foodstuffs already on the market (3000+)

- EFSA has been systematically evaluating these substances since 2002, based on available data
Safety assessment of flavourings in the EC

- Safety is assessed using the traditional risk assessment paradigm
  - hazard identification, hazard characterisation, exposure assessment, risk characterisation

- Limited opportunity to ask for safety data on the “old” flavouring substances

- Very limited information on actual exposure of the consumer
Risk Assessment of Flavouring Substances: General Principles

- Assignment of flavouring substances with common structural elements to compound classes (I - III) (Cramer et al., 1978)
- Comparison of intake to "thresholds of concern" for each class
- Assessment of potential metabolites
- Particular attention paid to genotoxicity

I. Non-genotoxic, innocuous metabolites and intake < "threshold of concern"
   ⇒ no safety concern at the estimated level of intake

II. potentially harmful metabolites and/or intake > "threshold of concern"
   ⇒ toxicological assessment
   NOAEL / adequate margin of safety
Safety assessment of flavourings in the EC

- Safety assessment is not as extensive as for e.g. food additives

- But:
  - ~ 3000 flavourings to assess
  - Exposure is generally very low
  - Many (most) flavourings occur naturally in food

- Risk is in reality very low
- EFSA opinion on risk (published)

- Safety, conditions of use and (?) maximum permitted levels in food discussed in Working Group on Flavouring Substances (governmental experts on flavourings)

- Agreement on these, substances added to the Community list
For new flavouring substances in the future there is requirement for specific data before the substance can be added to the Community list.
CONCLUSIONS

- Flavourings go through an extensive period of safety assessment and review before they are authorised for use in food in Europe

- A number of bodies involved in assessment (EFSA, European Commission, national experts, European Parliament) = multiple checks
Thank you!

Any questions?