

## Publication of the List of Flavouring substances in the Official Journal

**The Implementing Regulation establishing the List of Flavouring Substances has been adopted and published in the Official Journal along with the Regulation on transitional measures.**

### Adoption and Publication

- Two Regulations in relation to the Union List have been formally adopted on 1 October 2012 and published in the Official Journal on 2 October 2012:
  - The *Commission Implementing Regulation (EU) No 872/2012 adopting the list of flavouring substances provided for by Regulation (EC) 2232/96, [...] introducing it in Annex I to Regulation (EC) No 1334/2008* [OJ L 267/1], hereinafter referred to as “Implementing Regulation”;
  - The *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* [OJ L 267/162], hereinafter referred to as “Regulation on transitional measures”.
- The List of Flavouring Substances (Annex Part A to the Implementing Regulation) is the Part A of the Union List of Flavourings and Source Materials (Annex I to Regulation (EC) No 1334/2008).
- The Union List Part B to F covers the flavourings and source materials referred to in Article 9(b) to (f) of Regulation (EC) No 1334/2008.

### Entry into Force and Application of the Regulations and the Union List

- The Regulations will enter into force on the 20<sup>th</sup> day following their publication, i.e. 22 October 2012.
- The Regulation on transitional measures shall be binding in its entirety and directly applicable in all Member States, i.e. by 22 October 2012.
- The date of application of the Implementing Regulation and the Union List Part A will be 6 months after the date of its entry into force, i.e. on 22 April 2013.
- Article 10 of Regulation (EC) No 1334/2008 shall apply from 18 months after the date of application of the Union List Part A, i.e. 22 October 2014.
- Also all other provisions like restrictions of use and compliance with purity requirements shall apply from 22 October 2014 (i.e. Application of Art. 10 of Regulation (EC) No 1334/2008).
- Parts B to F of the Union List of flavourings and source materials shall apply from 22 October 2016.

### Transitional Measures

- **Part A: List of Flavouring Substances (hereinafter “the List”)**
  - Flavouring substances not included in the List may be placed on the market and used in or on food until 22 October 2014 (i.e. application of Art. 10 of Regulation (EC) No 1334/2008) and in addition dedicated transitional measures apply to foods containing flavouring substances which are not included in the List but which are lawfully placed on the market and labelled prior to 22 October 2014.
  - It is our understanding that compounded flavourings are also considered as foods and are covered by the same transitional measures as for foods.
  - The List will supersede the national positive lists by the date of its application, i.e. 22 April 2013.

➤ **Part B: Flavourings and Source Materials referred to in Article 9(b) to (f)**

- Foods containing flavourings and source materials which are lawfully placed on the market or labelled prior to 22 April 2018 but which do not comply with Parts B to F of the Union List, may be marketed until their date of minimum durability or use-by date.

### Content of the List of Flavouring Substances

- **The List contains 2543 flavouring substances** with the following information: **FL No** (unique identification number of the substance), **Chemical Name** of the substance, **CAS No**, **JECFA No**, **CoE No**, **Purity** (at least 95% unless otherwise specified), **Restrictions of Use** (if applicable), a **Reference** to the scientific body that has carried out the evaluation.
- The List consists of both **evaluated flavouring substances** and **flavouring substances** which are still **under evaluation** by EFSA. Although the latter substances are marked with a **footnote** in the List they are **deemed to be safe for use**:
  - Flavouring substances for which EFSA has not yet completed the evaluation and no request for additional information is pending, are identified as such by footnote 1.
  - Footnotes 2 to 4 have been assigned for those substances for which EFSA has requested additional scientific data. These footnotes refer to specific time limits in order to manage the submissions of additional scientific data requested by EFSA. A time limit is also set for EFSA to evaluate the submitted data.
- The List includes all flavouring substances, either natural or not, that are supported by the Industry.

### Restrictions of use of some flavouring substances in the List

- For **11 substances restrictions of use** apply in **specified food categories**, namely for d-camphor (FL 07.215), three quinine salts (FL 14.011, FL 14.152 and FL 14.155), glycyrrhizic acid (FL 16.012) and its ammoniated form (FL 16.060), caffeine (FL 16.016), theobromine (FL 16.032), ammonium chloride (FL 16.048), neohesperidin dihydrochalcone (FL 16.061) and rebaudioside A (FL 16.113), when used as flavouring substances. These substances may only be added to the listed food categories.
- The use of **all other substances** is permitted in accordance with **good manufacturing practices**.

### Purity of the flavouring substances

- All flavouring substances included in the List have to comply with a **Minimum Assay Value**: the **purity** of the named flavouring substance has to be **at least 95% unless otherwise specified**.

### Repeals

- Regulation No 2232/96/EC is repealed but continues to apply for substances with footnotes.
- Regulation No 1565/2000/EC is repealed but continues to apply for substances with footnotes.
- Decision No 1999/217/EC (**Register** of flavouring substances) is **repealed** and will not apply any longer.

We trust that this Information Letter will clarify any questions related to the Union List and provide you with clarity about the continued legality of selling and marketing flavourings for food in the EU marketplace.

Should you have any questions or comments on the above information, please as always feel free to contact us.