



EUROPEAN FLAVOUR & FRAGRANCE ASSOCIATION

EFFA Information Letter FL/09/01

Page 1/1

## **EFFA Guidance Document on the EC Regulation on Flavourings**

EFFA (European Flavour and Fragrance Association) has finalised its Guidance Document on the practical application of the new European legislation on flavourings which has been published as Regulation (EC) No 1334/2008 in the Official Journal on 31 December 2008. The Regulation will replace the Directive 88/388/EEC on flavourings which will be repealed by 20 January 2011.

The Guidance Document is built up of six chapters following the chapters of the Regulation. It highlights the major changes and seeks to establish EU wide industry guidance on the interpretation of the new rules that will serve as a reference to operators and enforcement authorities. The document also includes examples of the possible labelling of flavourings both for B2B sales and on final foodstuffs.

The Guidance Document is intended to help all flavouring manufacturers and food business operators to better understand the requirements of the new Regulation on flavourings. It has been produced to provide informal, non-binding advice on the new Regulation and should be read in conjunction with the legislation itself. Every effort has been made to ensure that this Guidance Document is as helpful as possible. However, it is ultimately the responsibility of the individual businesses to ensure their compliance with the law.

This Guidance Document is a “living” document and it will be updated on a regular basis. If you have further questions, please do not hesitate to contact EFFA at [info@effaorg.org](mailto:info@effaorg.org) or your respective national association. It is intended to publish “Questions and Answers” in a separate document. We welcome your questions.

19 February 2009



EUROPEAN FLAVOUR & FRAGRANCE ASSOCIATION

**EFFA Guidance Document on the EC Regulation on Flavourings**

**(19/02/09)**

## **EFFA Guidance Document on the EC Regulation on Flavourings**

### **General Introduction**

On July 8<sup>th</sup> the European Parliament (EP) voted for the FIAP (Food Improvement Agents Package) which includes a Regulation on Flavourings. The new EC Regulation on Flavourings<sup>1</sup> (hereinafter referred to as the “Regulation”) was published on December 31, 2008. The Regulation entered into force on January 20, 2009 and will be binding as of January 20, 2011. During these 24 months transitional period, current national legislation will still be in force.

EFFA (European Flavour and Fragrance Association) represents the European Flavour Industry and welcomes review and updating of the European flavourings legislation.

With EFFA **IL FL/09/01** EFFA distributed a document summarizing the major changes introduced in the new Regulation (See **Attachment I** to this Guidance Document).

The current EFFA Guidance Document further elaborates on the changes requiring interpretation and gives some further guidelines. It is intended to harmonise the interpretation of the Regulation within the European Flavour Industry and thus to serve fair competition.

It further seeks to establish EU wide guidance on the practical application of the new (EC) Regulation on Flavourings that will serve as a reference for operators and enforcement authorities.

EFFA underlines that producers of flavourings have the responsibility to produce and place on the market safe flavourings.<sup>2</sup> Certain flavourings should, therefore, undergo a risk assessment before they can be permitted in food. Furthermore, their use must not mislead the consumer and their presence in food should, therefore, always be indicated by appropriate labelling.<sup>3</sup>

---

<sup>1</sup> REGULATION (EC) No 1334/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC – OJ L 354, 31.12.2008, p. 34.

<sup>2</sup> See Chapter I and II of this Guidance Document.

<sup>3</sup> See Recital (7) of the Regulation.

This Guidance Document is built up of six Chapters following the Chapters of the Flavouring Regulation:

1. Chapter I Subject Matter, Scope and Definitions
2. Chapter II Conditions of Use
3. Chapter III Community List
4. Chapter IV Labelling of flavourings
5. Chapter V Procedural Provisions and Implementation – Reporting and Monitoring
6. Chapter VI Transitional and final Provisions – Entry into force and application.

Several attachments have been added to the present Guidance document in order to provide some examples or in order to clarify the interpretations expressed in the Guidance document.

### **Disclaimer**

#### **Important Legal Notice:**

The present Guidance Document on the Regulation has been produced by EFFA solely with the aim of providing informal guidance. It should be read in conjunction with the relevant legislation, it being understood that only European Union legislation published in paper editions of the Official Journal of the European Union is deemed authentic. The guidance given by EFFA should not be used as a substitute for legal advice and should not be considered as an authoritative interpretation of the law, as only the European courts have the power to interpret statutory provisions.

Everyone should be aware of and fulfill all their obligations under applicable national and European laws and regulations. The guidance given by EFFA does not relieve members or any other persons of their obligations under those laws and regulations and members and any other persons should always satisfy themselves in any particular instance that the guidance provided by EFFA can be properly followed.

The Guidance Document was established with great care. However, EFFA can not be held accountable for the correctness of information, suggestions, advice and possible printing errors.

EFFA nor any individual members or officers, can be held liable for any loss or damage suffered by any member or by any other person as a result of following or relying on this Guidance Document or other EFFA documentary materials.

By using this Guidance Document, you will be deemed to have accepted the above limitation of liability.

EFFA has the copyright for this Guidance Document. The reproduction of the total text or parts thereof is permissible only if title and author are named.

## Chapter I (Articles 1 and 2)

### Subject Matter and Scope

#### 1. Article 1 – Subject Matter of the Regulation

- Extended Scope

According to Article 1 the Regulation aims at laying down rules on **flavourings** (as defined in Article 3.2 (a) of the Regulation) and **food ingredients with flavouring properties** (as defined in Article 3.2 (i) of the Regulation) for use in and on foods. Thus, contrary to Directive 88/388/EEC<sup>4</sup> which restricted its scope to flavourings, the Regulation extends its scope to certain food ingredients with flavouring properties.<sup>5</sup>

- Policy objectives

The Regulation aims at achieving 5 complementary policy objectives,<sup>6</sup> of which **consumer health** and **consumer interests** appear to be the core objectives. Recital (7) of the Regulation emphasizes the importance of both the **appropriate labelling** (consumer interest) and the **risk assessment** (consumer health), while insisting that **other legitimate factors** (*inter alia* societal, economic, ethical or environmental factors), as well as the precautionary principle, should also be taken into account when approving flavourings.

- Regulatory framework

The Regulation provides for three regulatory tools aiming at achieving the policy objectives indicated above, i.e. (a) a **Community list** of flavourings and source materials approved for use in and on foods,<sup>7</sup> (b) a set of **specific conditions of use** of flavourings and food ingredients with flavouring properties in and on foods,<sup>8</sup> and (c) specific **rules on the labelling** of flavourings.<sup>9</sup>

---

<sup>4</sup> See OJ L 184, 15.7.1988, p.61.

<sup>5</sup> In its Explanatory Memorandum (See COM(2006) 427 final, 28.07.2006) the European Commission clarified that due to diverging practices of the Member States regarding the application of maximum levels for undesirable substances (either application of the maximum levels to food containing only flavourings or application of the maximum levels to food containing both flavourings food ingredients with flavouring properties) a harmonized approach should be reached through the extension of the scope. See also p. 5 of the Explanatory Memorandum, “Clarification of the Scope”.

<sup>6</sup> The 5 policy objectives are: a) ensuring an effective functioning of the internal market, b) ensuring a high level of human health protection, c) protecting consumer interests, d) ensuring fair practices in food trade and d) protecting the environment.

<sup>7</sup> See Chapter III of the Regulation (Articles 9–13) and Annex I of the Regulation and Chapter III of this Guidance Document.

<sup>8</sup> See Chapter II of the Regulation (Articles 4-8) and Chapter II of this Guidance Document.

<sup>9</sup> See Chapter IV of the Regulation (Articles 14-18, especially Article 16 laying down the conditions for the use of the term “natural”) and Chapter IV of this Guidance Document.

## 2. Article 2 – The Scope of the Regulation

Article 2 of the Regulation defines the scope both positively and negatively, i.e. it provides a **positive catalogue**<sup>10</sup> of items falling under its scope as well as a **negative catalogue**<sup>11</sup> of items not falling under its scope.

- The Regulation covers:<sup>12</sup>
  - **flavourings** (as defined Article 3.2 (a) of the Regulation) which are used or intended to be used in or on foods;<sup>13</sup>
  - **food ingredients with flavouring properties** (as defined in Article 3.2 (i) of the Regulation);
  - **food** containing flavouring and/or food ingredients with flavouring properties;
  - **source materials** (as defined in Article 3.2 (j) of the Regulation) for flavourings and/or source materials for food ingredients with flavouring properties.
- The Regulation does not cover:<sup>14</sup>
  - **substances which have exclusively a sweet, sour or salty taste**, such as all sugar categories, sweeteners, salt (sodium chloride), citric acid;
  - **raw foods**;<sup>15</sup>
  - **non-compound foods and mixtures** such as, but not exclusively, fresh, dried or frozen spices and/or herbs, mixtures of tea and mixtures for infusion as such, **as long as they have not been used as food ingredients**, e.g. cinnamon sticks, cherry juice.

---

<sup>10</sup> See Article 2.1 of the Regulation.

<sup>11</sup> See Article 2.2 of the Regulation.

<sup>12</sup> See also Recital (5) of the Regulation clarifying the scope of the Regulation.

<sup>13</sup> It should be noted that “smoke flavourings” (as defined in Article 3.2 (f) of the Regulation) are also subject to the more specific rules laid down in Regulation (EC) No 2065/2003 (See OJ L 309, 26.11.2003, p.1).

<sup>14</sup> See also Recital (6) of the Regulation clarifying the scope of the Regulation.

<sup>15</sup> According to Recital (6), “raw foodstuffs” are products not having undergone any processing treatment.

## Chapter I (Article 3)

### Definitions

#### Introduction

Flavourings are used to impart or modify the odour and/or taste of foods.<sup>16</sup> Flavourings may contain food additives as permitted by Regulation (EC) No. 1333/2008<sup>17</sup> and/or other food ingredients incorporated for technological purposes.<sup>18</sup>

Flavourings are not intended to be consumed as such.

Flavouring components, as mentioned in Article 29 are considered to be the different categories of flavourings as described in Article 3.2. b) – h). With respect to certain categories of flavourings and corresponding definitions EFFA provides further guidance below.

Only flavourings belonging to the categories “natural flavouring substances” as defined in Article 3.2 (c) and “flavouring preparations” as defined in Article 3.2 (d) can be labelled with the term “natural”.<sup>19</sup>

#### 1. Flavouring substance (Article 3.2 (b))

The category “flavouring substance” comprises all 3 categories referred to in Directive 88/388/EEC, i.e. natural flavouring substances, nature-identical flavouring substances and artificial flavouring substances.<sup>20</sup> The denominations “nature-identical” and “artificial” (and the distinction between them) no longer exist.

A flavouring substance is obtained from materials of vegetable, animal, microbiological or mineral origin. For ‘natural flavouring substances’ more specific rules<sup>21</sup> apply (See Section 2 below).

Salts of flavouring substances keep the status of the generic substance.<sup>22</sup>

#### 2. Natural Flavouring substances (Article 3.2 (c))

A flavouring substance is considered to be ‘natural’ when it is obtained from material of vegetable, animal or microbiological origin, by natural processes, **and** has been “identified in nature”.

---

<sup>16</sup> See Article 3.2 (a) (i) of the Regulation.

<sup>17</sup> See Regulation (EC) No. 1333/2008/EC, OJ L 354, 31.12.2008, p. 16.

<sup>18</sup> See Article 3.4 of the Regulation.

<sup>19</sup> See Article 16.2 of the Regulation and Chapter IV of this Guidance Document.

<sup>20</sup> See Article 1.2 (b) and Article 9.1 (d) of Directive 88/388/EEC on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production, OJ L 184, 15.7.1988, p. 61.

<sup>21</sup> See Article 3.2 (c) of the Regulation.

<sup>22</sup> Commission Decision 1999/217/EC, adopting a Register of Flavouring substances, OJ L 84, 27.3.1999, p. 1.

EFFA is seeking to provide further guidance on the source materials and natural processes that can be used to obtain ‘natural flavouring substances’

“Identified in nature” means:

- identified in materials of plant, animal, microbiological, or mineral origin,<sup>23</sup> and/or
- identified in food in the raw state or processed or partly processed for human consumption and
- meeting the criteria for the validity of identifications in nature as further described in the attachment to IOFI Information Letter 1333 (*Flavour Fragr. J.*, 2006, **21**: 185).

Substances which do not meet the abovementioned requirements shall not be considered as being natural.

### 3. Flavouring preparation (Article 3.2 (d))

According to the Regulation “flavouring preparations” are products other than chemically defined substances which meet the definition of flavouring materials and which are obtained from food or other material of vegetable, animal or microbiological origin by appropriate physical processes or enzymatic or microbiological processes either in the raw state of the material thus derived or after further processing for human consumption by one of the traditional food preparation processes listed in Annex II.<sup>24</sup>

ISO Standard 9235 gives some examples of different flavouring preparations such as essential oils, extracts and tinctures.<sup>25</sup>

The new definition of flavouring preparations:

- makes a distinction between those that are made from foods and those that are made from non-foods (a distinction that becomes an important factor in deciding whether the flavouring preparation shall be subject to special evaluation and authorization prior to use).<sup>26</sup>
- no longer includes the words “*whether concentrated or not*”.<sup>27</sup> The significance of this deletion is not considered to exclude preparations that are concentrated (such as deterpenated citrus oils) or are diluted due to the presence of intrinsic water (e.g. as in juice-derived preparations) or the presence of residual extraction solvents. The presence of intrinsic water and/or residual extraction solvents should not be in conflict with the flavouring properties and should be in line with Good Manufacturing Practice (GMP) and where applicable comply with

---

<sup>23</sup> “Identified in nature”, should not be confused with “recognised as a source material” for the production of natural flavouring substances or flavouring preparations, e.g. mineral origin (should not be regarded as a source material). This topic is covered in the definition of source material (Paragraph 8 of this Chapter).

<sup>24</sup> See Article 3.2 (d) of the Regulation. Please also refer to Recital (15) of the Regulation.

<sup>25</sup> International Organization for Standardization (ISO): International Standard 9235 – Aromatic natural raw materials – Vocabulary. ISO 1997©.

<sup>26</sup> See Article 8 and Article 9 (b) of the Regulation and Chapter III of this Guidance Document

<sup>27</sup> See Article 1.2 (c) of Directive 88/388/EEC.

prescribed levels.<sup>28</sup> The presence of ingredients such as water, ethanol or vegetable oils that are residual in the flavouring preparation after having been used as extraction solvents (but not subsequently added as agents for diluting or dissolving them) and which are carried over in the flavouring preparations, are considered as part of the "flavouring preparation".

- refers to "*traditional food preparation processes*", listed in Annex II;
- refers to "*appropriate physical process*" as defined in Article 3.2 (k);
- refers to "*processing for human consumption*" which is not restricted to increasing safety, digestibility or improving nutritional characteristics but also includes increasing palatability and improving taste and flavour characteristics provided that these do not mislead the consumer.

#### 4. Thermal process Flavouring (Article 3.2 (e))

Thermal process flavouring is obtained by processes such as 'the Maillard reaction'. This type of flavouring agent has a complex composition which is comparable to the composition of cooked, baked (or similarly produced) kitchen prepared food. It is the result of heating a blend of an amino containing ingredient (nitrogen source) and a reducing sugar.

Examples of nitrogen sources include Amino acids and their salts, peptides, proteins from foods, hydrolysis products of those proteins. Reducing sugars are e.g. dextrose/glucose, xylose.

The process conditions applied to such mixtures are specified in Annex V of the Regulation and are not part of the definition. It should be underlined that any thermal process flavouring not produced according to the conditions specified in Annex V needs specific evaluation and authorization.<sup>29</sup>

It is the responsibility of the flavour producing company to judge whether or not the conditions used for their production are compliant with the conditions set out in Annex V.

#### 5. Smoke Flavouring (Article 3.2 (f))

Smoke flavourings are regulated in Regulation (EC) No 2065/2003:<sup>30</sup>

The following products fall under the definition of a 'smoke flavouring':

1. 'primary smoke condensate' shall refer to the purified water-based part of condensed smoke and shall fall within the definition of 'smoke flavourings';
2. 'primary tar fraction' shall refer to the purified fraction of the water-insoluble high-density tar phase of condensed smoke and shall fall within the definition of 'smoke flavourings';

<sup>28</sup> Directive 88/344/EEC of 13 June 1988 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients (OJ L 157, 24.6.1988, p. 28).

<sup>29</sup> See Article 9 (c) of the Regulation.

<sup>30</sup> OJ L 309, 26.11.2003, p. 1.

3. 'primary products' shall refer to primary smoke condensates and primary tar fractions;
4. 'derived smoke flavourings' shall refer to flavourings produced as a result of the further processing of primary products and which are used or intended to be used in or on foods in order to impart smoke flavour to those foods.

Information on the status of the evaluation of primary products is available on the Commission's website.

## 6. Flavour precursor (Article 3.2 (g))

Flavour precursors are products that do not necessarily have flavouring properties themselves but are **intentionally** added to food for the purpose of producing flavour by breaking down / reacting with other components during processing of the food.

When flavour precursors are obtained from **food** they do not need to be evaluated and approved.

Examples of flavour precursors include:

- Carbohydrates, oligopeptides and amino acids.

Some flavour precursors belong to different flavouring categories, e.g., amino acids can be used as flavour precursors but some are also on the Community Register as flavouring substances. Precursors can be single substances or mixtures.

## 7. Other Flavouring (Article 3.2 (h))

In cases where a flavouring material does not fit the definition of flavouring substances, flavouring preparations, thermal process flavourings, smoke flavourings or flavour precursors, it is automatically classified as 'other flavouring'.

Other flavourings always require an evaluation and approval.<sup>31</sup>

Rum ether is regarded as an example of the "other flavourings" category.

## 8. Source material (Article 3.2 (j))

Source material shall mean material of vegetable, animal, microbiological or mineral origin from which flavourings or food ingredients with flavouring properties are produced. Source materials can be food or non food.<sup>32</sup>

According to Regulation 178/2002/EC,<sup>33</sup> food is considered as any substance or product, whether processed, partially processed or unprocessed, intended to be, or

---

<sup>31</sup> See Article 9 (e) of the Regulation and Chapter III of this Guidance Document.

<sup>32</sup> See Article 3.2 (j) of the Regulation.

<sup>33</sup> See Article 2 of Regulation (EC) No 178/2002 ("General Food Law") OJ L 31, 1.2.2002, p. 1.

reasonably expected to be ingested by humans.<sup>34</sup> Materials of vegetable, animal, microbiological and mineral origin for which it can sufficiently be demonstrated that they have been used for the production of flavourings are also considered to be food in this context.<sup>35</sup> This is considered to take account of materials used anywhere worldwide<sup>36</sup> for these purposes prior to the date of entry into force of the Regulation.<sup>37</sup>

Any other material will be considered as non-food and will have to be evaluated when used as a source material for flavouring preparations, thermal process flavourings or flavour precursors in accordance with the Regulation.<sup>38</sup>

Source materials listed in Part A of Annex IV<sup>39</sup> shall not be used for the production of flavourings and/or food ingredients with flavouring properties. The restriction on the use of certain source materials is covered by Chapter II of this Guidance Document.<sup>40</sup>

---

<sup>34</sup> This includes sources amongst others those mentioned in Fenaroli's Handbook of Flavor Ingredients (5th Ed., volume I) by CRC Press Inc, Boca Raton, FL 2005; Natural Sources of Flavourings, Council of Europe, 2008, 2007 & 2000; CFR, Title 21, parts 172.510, 182 and 184; Tanaka's Encyclopedia of Edible Plants of the World, Tyôzaburô, Tanaka Keigaku Publishing co, Tokyo, 1976.

<sup>35</sup> See Article 3.3 of the Regulation. Please also refer to Recital (16) of the Regulation.

<sup>36</sup> No restriction is made in the Regulation limiting this only to the European Union.

<sup>37</sup> The 20 January 2009 is the date of the entry into force of the Regulation.

<sup>38</sup> See Article 9 of the Regulation.

<sup>39</sup> Tetraploid form of *Acorus calamus* L.

<sup>40</sup> See Article 7 of the Regulation and Chapter II of this Guidance Document.

## Chapter II (Articles 4–7)

### Conditions for Use of Flavourings, Food Ingredients with Flavouring Properties and Source Materials

#### 1. Introduction

Since 1999, the Scientific Committee on Food (SCF) and subsequently the European Food Safety Authority (EFSA) have expressed respective opinions on a number of substances occurring naturally in source materials for flavourings and food ingredients with flavouring properties, e.g. herbs, spices, which, according to the Committee of Experts on Flavouring Substances of the Council of Europe (CoE)<sup>41,42</sup>, raise toxicological concern. The common name for those substances used within the food industry is “Biologically Active Principles” (so-called “BAPs”) or “Active Principles”. For this reason, these restricted substances will also be referred to as “BAPs” or “Active Principles” in this Guidance Document.

#### 2. The new Regulation

With reference to the Regulation substances for which the toxicological concern was confirmed by SCF/EFSA should be regarded as naturally occurring undesirable substances which should not be added as such to food.<sup>43</sup> Due to their natural occurrence in plants, these substances might be present in flavourings and certain food ingredients with flavouring properties.<sup>44</sup>

##### 2.1. Scope<sup>45</sup>

The Regulation clarifies in its title that it also covers certain food ingredients with flavouring properties. These are defined as food ingredients other than flavourings which may be added to food for the main purpose of adding flavour to it or modifying its flavour and which contribute significantly to the presence in food of certain naturally occurring undesirable substances.<sup>46</sup>

Consequently Annex III part B of the Regulation refers to maximum levels of “BAPs”, naturally present in flavourings and food ingredients with flavouring properties, in certain compound food as consumed to which flavourings and/or food ingredients with flavouring properties have been added.

---

<sup>41</sup> Within CoE a Committee of Experts on Flavouring Substances has evaluated the safety-in-use of natural flavouring source materials since 1970. The results are published in the “Blue Book” – Flavouring Substances and Natural Sources of Flavourings, Council of Europe.

<sup>42</sup> According to CoE “active principles” are chemically defined substances which occur in certain natural flavouring source materials and preparations and which, on the basis of existing toxicological data, should not be used as flavouring substances in their own right. Source: Active principles (constituents of toxicological concern) contained in natural sources of flavourings – approved by the Committee of Experts on Flavouring Substances, October 2005.

<sup>43</sup> See Recital (8) of the Regulation.

<sup>44</sup> See Recital (9) of the Regulation.

<sup>45</sup> See also Chapter I of this Guidance Document under Scope.

<sup>46</sup> See Article 3.2 (i) of the Regulation.

## 2.2. Risk management for Annex III - substances

### 2.2.1 General conditions

Only flavourings or food ingredients with flavouring properties which meet the following conditions may be used in or on foods:

- they do not, on the basis of the scientific evidence available, pose a safety risk to the health of the consumer and
- their use does not mislead the consumer.<sup>47</sup>

Products (flavourings and/or food) which do not comply with this Regulation are prohibited.<sup>48</sup>

### 2.2.2 Annex III part A – list of substances which shall not be added as such to food

A general list of 15 substances that should not be added as such to foods (including flavourings and food ingredients with flavouring properties) is provided in Annex III part A:<sup>49</sup>

- Agaric acid
- Aloin
- Beta-asarone
- Capsaicin (new)
- Coumarin
- Estragole (new)
- Hydrocyanic acid
- Hypericine
- Menthofuran (new)
- Methyleugenol (new)
- Pulegone
- Quassin
- Safrole<sup>50</sup>
- Teucrin A (new)
- Thujone (alpha und beta).

According to the first principle of HACCP (Hazard Analysis and Critical Control Point) as laid down in Regulation 852/2004/EC,<sup>51</sup> the flavour manufacturers shall put in place suitable procedures in order to identify any hazard that must be prevented, eliminated or reduced to acceptable levels.

#### **Recommendation:**

**Flavour producers commit themselves to control the potential presence of ANNEX III A substances in flavourings. In the Quality Assurance System of flavour producers, these substances should be identified as “hazard”.**

<sup>47</sup> See Article 4 of the Regulation.

<sup>48</sup> See Article 5 of the Regulation.

<sup>49</sup> Nota bene: Berberin and santonin are no longer mentioned in this list.

<sup>50</sup> According to the SCF opinion, “any measure to restrict exposure to safrole in food would also cover isosafrole”. SCF Opinion on isosafrole, expressed on 4 April 2003 (SCF/CS/FLAV/FLAVOUR/30 Final).

<sup>51</sup> See Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs, OJ L 139, 30.4.2004, p. 1.

### 2.2.3 Annex III part B – maximum levels of certain substances

The risk management of certain substances naturally present in certain food ingredients with flavouring properties and/or flavourings is based upon the “major contributor approach”, i. e.:

Maximum levels<sup>52</sup> are established for the presence of these undesirable substances in foods which are presumed to contribute most to the human intake of these substances, taking into account both the need to protect human health and their unavoidable presence in traditional foods.<sup>53</sup>

- Maximum levels for certain naturally occurring undesirable substances should focus on the food or food categories which contribute most to dietary intake.<sup>54</sup>
- Only food ingredients with flavouring properties contributing significantly to the presence in food of certain naturally occurring undesirable substances are considered.<sup>55</sup>

For those foodstuffs not listed in this Annex, the general rules for safety apply.<sup>56</sup>

Annex III part B sets maximum levels for the following 11 substances:<sup>57</sup>

- Beta-asarone
- Coumarin
- Estragole (new)
- Hydrocyanic acid
- Menthofuran (new)
- Methyleugenol (new)
- Pulegone
- Quassin
- Safrole<sup>58</sup>
- Teucrin A (new)
- Thujone (alpha and beta).

The maximum levels of these substances shall apply to foods as marketed, unless otherwise stated. By way of derogation from this principle, for dried and/or concentrated foods which need to be reconstituted, the maximum levels shall apply to the food as reconstituted according to the instructions on the label, taking into account the minimum dilution factor.<sup>59</sup>

#### **Recommendation:**

**Flavour Companies commit themselves to communicate to the customer any relevant “BAPs” levels in flavourings irrespective of the intended use of the flavourings, preferably also if the flavoured food is not covered by any food category mentioned in Annex III B.**

<sup>52</sup> The maximum levels shall not apply to estragole, methyleugenol and safrole where a compound food contains no added flavourings and the only food ingredients with flavouring properties that have been added are fresh, dried or frozen herbs and spices.

<sup>53</sup> See Recital (9) of the Regulation.

<sup>54</sup> See Recital (10) of the Regulation.

<sup>55</sup> See Article 3.2 (i) of the Regulation.

<sup>56</sup> See Article 14 of EC Regulation 178/2002 – EC Basis Regulation on Food Law.

<sup>57</sup> No maximum levels are set anymore for agaric acid, aloin, berberin, hypericine and santonin; however with reference to agaric acid and hypericine Annex IV has to be taken into account.

<sup>58</sup> According to the SCF opinion, “any measure to restrict exposure to safrole in food would also cover isosafrole”. SCF Opinion on isosafrole, expressed on 4 April 2003 (SCF/CS/FLAV/FLAVOUR/30 Final).

<sup>59</sup> See Article 6.2 of the Regulation.

## 2.2.4 Monitoring and Reporting by Member States<sup>60</sup>

Member States shall establish systems to monitor the consumption of “BAPs” listed in Annex III on a risk-based approach, and shall report their findings with appropriate frequency to the Commission and to EFSA. A common methodology for gathering the data shall be adopted by 20 January 2011.<sup>61</sup>

### **Recommendation:**

**Flavour Companies commit themselves to communicate to the Commission and Member States respectively all relevant data if needed.**

## 2.2.5 Annex IV – List of source materials to which restrictions apply

Provisions should be established at Community level in order to prohibit or restrict the use of certain plant, animal, microbiological or mineral materials which raise concern for human health in the production of flavourings and food ingredients with flavouring properties and their application in food production.<sup>62</sup>

Source materials listed in Part A of Annex IV shall not be used for the production of flavourings and/or food ingredients with flavouring properties.<sup>63</sup> For the time being there is only one source material listed: Tetraploid form of *Acorus calamus* L.<sup>64</sup>

### **Recommendation:**

**Flavour companies should ask for confirmation about the absence of tetraploid form of *Acorus calamus* L. in calmus oil. “Active principle” in calmus oil is Beta-sarone.**

Flavourings and/or food ingredients with flavouring properties produced from source materials listed in Part B of Annex IV may be used only under the conditions indicated in that Annex.<sup>65</sup> These source materials are (common names):

- Quassia for beverages and bakery wares (mind the limits for quassin)
- White agaric mushroom for alcoholic beverages
- St. John’s wort for alcoholic beverages
- Wall germander for alcoholic beverages (mind the limits for teucriin A)

<sup>60</sup> See also Chapter V of this Guidance Document (Monitoring).

<sup>61</sup> See Article 20 of the Regulation.

<sup>62</sup> See Recital (11) of the Regulation.

<sup>63</sup> See Article 7.1 of the Regulation.

<sup>64</sup> Article 22 allows amendments to Annexes II to V (see Chapter VI of this EFFA Guidance).

<sup>65</sup> See Article 7.2 of the Regulation.

### 2.2.6 Recommended analytical methods/criteria

The Working Group on Methods of Analysis (WGMA) of IOFI published a number of methods in the 70s and 80s for the determination of many of the Annex III restricted substances in beverages and foodstuffs. However, most of these methods are now considered as obsolete by the WGMA, with the possible exception of the last group<sup>66</sup> for which a satisfactory validation study was performed for safrole and pulegone.

In addition, a decision was adopted some time ago within the WGMA to limit recommendations and criteria for methods of analysis for these restricted substances to the actual flavourings, rather than to attempt proposing methods for their determinations in finished foods. While any methodology for flavourings could potentially be adapted for application to beverages, and even other food products which can be rendered in a homogenous liquid form without possible interference from the matrices, this is a matter for the end-user of the flavourings.

In recent years the WGMA has focussed on guidelines for different analytical approaches for the analysis of flavourings, such as qualitative and quantitative capillary GC, GC/MS with selected-ion monitoring (SIM), etc. The latter approach is particularly important in the context of the Annex III restricted substances, since it has become essential to ensure that the identification of these substances is confirmed by another method, particularly when present at low levels in a complex matrix.

With this in mind, the WGMA has developed a “multi-residue” approach for the volatile substances of Annex III, with the exception of hydrocyanic acid, for which classical wet-chemistry methodology or ion chromatography needs to be used.<sup>67</sup> This approach uses GC/MS with selected-ion monitoring, which enables the simultaneous quantification and unequivocal identification of the relevant compounds to be made, and has been applied successfully in the analogous situation of the quantification of suspected volatile allergens in fragrances.<sup>68</sup> This draft methodology for the Annex III restricted substances is currently undergoing evaluation in several flavouring-industry laboratories, and a wider inter-laboratory validation study will be initiated shortly.

The two remaining restricted (non-volatile) substances listed in Annex III are quassin and teucrin A. Both of these originate from single botanical sources and occur less frequently in flavourings; a few methods using HPLC have been published relatively recently,<sup>69,70</sup> and will be evaluated by the WGMA at its March 2009 meeting.

---

<sup>66</sup> IOFI (WGMA), *Z. Lebensm. Unters. Forsch.*, **186**, 36-38 (1988).

<sup>67</sup> Salagoity *et al.*, *Ann. Falsif. Exp. Chim. Tox.*, **95** (958), 71-77 (2002).

<sup>68</sup> Bassereau *et al.*, *J. Agric. Food Chem.*, **55**, 25-31 (2007).

<sup>69</sup> Vitanyi *et al.*, *Rapid communications in Mass Spectrometry*, **11**, 691-693 (1997).

<sup>70</sup> Bosisio *et al.*, *Food Additives and Contaminants*, **21** (5), 407-414 (2004).

## Chapter III (Articles 9–12)

### Community List

This Chapter relates to the **Community List of Flavourings and Source Materials Approved for Use in or on Foods**.<sup>71</sup>

It lays down the provisions for the inclusion of flavourings and source materials approved for use in or on foods in the Community list and defines for which flavourings and source materials an approval is required.

As soon as established, the Community List of flavourings and source materials approved for use in and on foods will be added to Annex I of the Regulation. Currently this Annex is empty.

**Article 9** of the Regulation refers to flavourings and source materials for which an evaluation and approval is required. These are:

- Flavouring substances,
- Flavouring preparations obtained from non-food materials,
- Thermal process flavourings obtained by heating ingredients from non-food sources and/or deviating from the conditions for the production set out in Annex V and/or exceeding the maximum levels for certain undesirable substances set out in Annex V,
- Flavour precursors obtained from source materials other than food,
- Other flavourings,
- Source materials other than food.

For more information regarding the definitions of these flavourings and source materials please refer to Chapter I of this Guidance Document under Art. 3 – Definitions.

**Article 10** of the Regulation refers to the purpose of the Community List.

In the future only those flavourings and source materials falling under Article 9 which are included in the Community list may be placed on the market as such and used in or on foods.

For more information regarding the application of Art. 10 of the Regulation, please refer to Chapter VI – Transitional and final provisions, Section 3 of this Guidance Document.

**Article 11** of the Regulation refers to the conditions for inclusion of flavourings and source materials in the Community list and defines the procedure for its amendment.

The inclusion of flavourings and source materials as well as the procedure for the amendment of the Community list has to be done in accordance with the “Common Authorisation Procedure” as laid down in Regulation (EC) No 1331/2008.<sup>72</sup>

---

<sup>71</sup> See Articles 9-12 of the Regulation.

<sup>72</sup> Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a Common Authorisation Procedure for food additives, food enzymes and food flavourings, OJ L 354, 31.12.2008, p. 1.

The current text of the Common Authorisation Procedure (CAP) lays down the procedural frame for the assessment and authorisation for all ingredients which are subject to evaluation and authorisation under each sectoral food law before they may be placed on the market.<sup>73</sup>

It is important to note that the implementing measures for CAP defining the format and content of an application and data required for the risk assessment of the substances concerned still need to be established and adopted<sup>74</sup>.

Until the implementing measures have been adopted (by January 20, 2011 at the latest) the interim procedure for the submission of a dossier of a new flavouring substance still applies, as outlined in EFFA's Guidance Document for the submission of a dossier for the evaluation of a new flavouring substance [**FL/06/05-FIN**]. This is available upon request.

**Article 12** of the Regulation provides that flavourings or source materials falling within the scope of Regulation (EC) No 1829/2003 on genetically modified food and feed should be authorised in accordance with both this Regulation (Flavourings) and the Regulation (EC) 1829/2003/EC.<sup>75</sup>

Flavourings which are already listed on the Community list do not require a new authorisation under this regulation if they are produced from a genetically modified source which is covered by an authorisation in accordance with (EC) No 1829/2003.

For additional information regarding this **Community List** please refer to the EFFA **Information Letter IL FL/08/01-upd** (See **Attachment II** to this Guidance Document).

## **Attachment II: IL/08/01-upd**

---

<sup>73</sup> See Article 1.1 of Regulation 1331/2008/EC (CAP).

<sup>74</sup> See Article 9.2 of Regulation 1331/2008/EC (CAP).

<sup>75</sup> OJ L 268, 18.10.2003, p.1.

## Chapter IV (Articles 15–17 and Article 29)

### Labelling of Flavourings

#### 1. Objective

The interpretation of the labelling rules for flavourings (Articles 15, 16, 17 and 29) respects the principles of the Regulation, should be simple and help identifying the most appropriate labelling for flavourings. EFFA's guidance on labelling and natural labelling in particular, must not mislead customers and consumers, be clear and easy to understand, transparent, and closely aligned with market perceptions.

#### 2. General labelling requirements for flavourings

##### 2.1. Labelling B2B – Labelling of flavourings not intended for sale to the final consumer

The 'business to business' (B2B) labelling requirements for flavourings are stipulated in Article 15. These requirements are similar to those laid down in Directive 88/388/EEC<sup>76</sup> with three additions. These require that *a date of minimum durability or use-by-date and allergen information according to the food labelling Directive<sup>77</sup> as amended*, and, if necessary, *the special conditions for storage and/or use* need to be mentioned on a label on the packaging of the product. It is not sufficient that this information is only provided on the accompanying documents.

##### 2.2. Labelling B2C – Labelling of flavourings intended for sale to the final consumer

In Article 17 the rules for the labelling of flavourings intended for sale to the final consumer are provided. The requirements for this 'Business to Consumer' (B2C) labelling refer to directives and regulations (and amendments thereof) that are relevant for food labelling.

The B2C-rules and the rules for the designation in the ingredient list of final food for labelling flavourings as 'natural' are equivalent to the rules that apply to B2B. These rules are provided in Article 16.

##### 2.3. Labelling of flavourings on the final consumer product

The rules for the labelling of flavourings on the consumer product are provided in Article 29. The final labelling is the responsibility of the food manufacturer. In case of uncertainty it is recommended to consult the flavour supplier for additional information or help.

---

<sup>76</sup> Council Directive of 22 June 1988 on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production – OJ L 184, 15.7.1988, p. 61.

<sup>77</sup> Directive 2000/13/EC of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs – OJ L 109, 6.5.2000, p. 29.

The B2C-rules and the rules for the designation in the ingredient list of final food for labelling flavourings as 'natural' are equivalent to the rules that apply to B2B. These rules are provided in Article 16.

Note on general labelling requirements: examples of labelling flavourings are given in the Attachment III and a Flow Chart is given for additional guidance in Attachment IV.

### 3. Labelling of flavourings

'Flavourings' or 'a more specific name or description of the flavouring', continue to be authorised terms. Examples of 'more specific names or descriptions of the flavouring' are: 'apple flavouring', 'banana flavouring', 'roasted chicken flavouring', and others, where an indicator of the flavour-profile is added to the sales description. Where applicable (i.e. where the composition of the flavouring does allow) specific names such as 'orange oil', 'lemon oil', 'yeast extract', 'spice extracts', and others, remain authorised.

### 4. Labelling of smoke flavourings

When flavouring materials are used that are defined as 'smoke flavourings' and at the same time add a smoky taste, the term 'smoke flavouring(s)' or 'smoke flavouring(s) produced from <<food(s) or food category or source(s)>>' should appear separately in the ingredient listing of the final food. An example of the last category is 'smoke flavouring produced from beech'.

### 5. Natural labelling

The overall condition that needs to be met is that the flavouring component<sup>78</sup> can only contain natural flavouring substances and/or flavouring preparations. There are 4 terms for the sales description of natural flavourings (see Article 16 paragraphs 3-6). The use of these terms is optional, since 'flavouring' or 'a more specific name or description of the flavouring' remains possible.<sup>79</sup>

#### 5.1. Natural flavouring substances

Article 16.3: The term "natural flavouring substance(s)" may only be used for flavourings in which the flavouring component contains exclusively natural flavouring substances.

The term '*natural flavouring substances*' is authorised for use if the flavouring component only contains flavouring materials that fit the definition 'natural flavouring substance'. If preferred and if applicable, the term '*natural <<X<sup>80</sup>>> flavourings*', '*natural <<X>> flavouring with other natural flavourings*' or '*natural flavouring*' may be used as an alternative.

<sup>78</sup> The flavouring component: i.e. materials that fit the definition of the flavouring categories as defined in Article 3.2. Article 3.2 (c) defines 'natural flavouring substances'. Article 3.2 (d) defines 'flavouring preparations'.

<sup>79</sup> See Article 15.1 (a) of the Regulation.

<sup>80</sup> <<X>> stands for <<food(s) or food category or source(s)>>.

## 5.2. Natural <<X>> flavouring

Article 16.4: The term "natural" may only be used in combination with a reference to a food, food category or a vegetable or animal flavouring source if the flavouring component has been obtained exclusively or by at least 95% by w/w from the source material referred to.

The description shall read "natural <<food(s) or food category or source(s)>> flavouring".

The flavouring component should consist of at least 95% by w/w of the source material and the flavour perception of the named source needs to be easily recognized<sup>81</sup>.

Recital (26) of the Regulation refers to the other 5% flavouring materials. This text is interpreted as follows: As the use of flavourings should not mislead the consumer concerning the source materials used for the production of natural flavourings, the other maximum 5 % by w/w from other sources should only be used to adjust natural variations in the flavour-profile to ensure a consistent quality and/or to introduce special notes to the flavouring such as a more fresh, pungent, ripe or green note and/or to modify the flavour-profile.

The above requirement is also known as the '95/5-rule'.

### Natural <<X and Y>> flavouring

It is possible to label flavourings as e.g. '*natural <<strawberry and vanilla >> flavouring*' when the total source material from strawberry and vanilla is at least 95% by w/w of the flavouring component. The flavour perception of the named sources needs to be easily recognised<sup>81</sup>. In line with the labelling requirements, the major contributor by weight needs to be mentioned first.

## 5.3. Natural <<X>> flavouring with other natural flavourings

Article 16.5: The term "natural <<food(s) or food category or source(s)>> flavouring with other natural flavourings" may only be used if the flavouring component is partially derived from the source material referred to, the flavour of which can easily be recognised.

To label a flavouring as '*natural <<X>> flavouring with other natural flavourings*' it is required that flavouring materials derived from the named source(s) are present<sup>82</sup> and that their flavour can easily be recognised<sup>81</sup>. Decisions on the fulfilment of these requirements and consequently if the use of above term is appropriate, will be made on a case-by-case basis at company level. In case of uncertainty, i.e. if the source(s) cannot easily be recognised, it is recommended to use the labelling '*natural flavouring*'.

<sup>81</sup> It is recognized that different flavouring materials have different sensorial thresholds and that flavour-perception cannot be quantified easily. The qualification for meeting the requirement 'can easily be recognized' will therefore be based on expert opinion, by e.g. a flavourist or a sensory panel evaluating the consumer product. The labelling of consumer products is the responsibility of the food manufacturer.

<sup>82</sup> Recital (26) mentions an upper limit in the flavouring component of less than 95% by weight. A lower limit is not provided.

### Natural <<X and Y>> flavouring with other natural flavourings

It is possible to label flavourings as e.g. '*natural <<strawberry and vanilla >> flavouring with other natural flavourings*' when source material from strawberry and vanilla is present. The flavour perception of strawberry and vanilla needs to be easily recognised<sup>81</sup>. In line with the labelling requirements, the major contributor by weight needs to be mentioned first.

#### **5.4. Natural flavouring**

Article 16.6: The term "natural flavouring" may only be used if the flavouring component is derived from different source materials and where a reference to the source materials would not reflect their flavour or taste.

The term '*natural flavouring*' is only available for flavourings when a clear relationship between the different source materials used in the flavouring component and the overall flavour-profile does not exist. Also in case of uncertainty about this relationship, it is recommended to use the term '*natural flavouring*'.

Please also refer to **Attachment III** (Examples of labelling flavourings) and **Attachment IV** (Flow chart for labelling) of this Guidance Document.

## Chapter V (Articles 19 and 20)

### Procedural Provisions and Implementation Reporting and Monitoring

Chapter V “Procedural Provisions and Implementation” of this Regulation mainly focuses on reporting that has to be carried out by the food business operators<sup>83</sup> and by the Member States.<sup>84</sup> As rules for implementation of paragraph 1 of Article 19 and a common methodology for the gathering of data by Member States are not available yet the following remarks are preliminary.

#### 1. Article 19 – Reporting by the food business operators

**Paragraph 1** only refers to reporting by food business operators of flavouring substances as it is explained in Recital (28):

*“For the evaluation of the safety of flavouring substances for human health, information on the consumption and use of flavouring substances is crucial. The amounts of flavouring substances added to food should therefore be checked on a regular basis.”*

This is the reason why at the request of the Commission, a producer or user of a flavouring substance (or their representative) will inform the Commission of the amount of the flavouring substance added to foods in the European Union in a period of 12 months (European poundage data).

This information will be kept confidential insofar as it is not required for the safety assessment<sup>85</sup>. In some cases, the food industry together with the flavour industry will have to provide use levels for some specific food categories to the Commission, as referred to in Regulation 1565/2000.<sup>86</sup> This information shall be made available to Member States.<sup>87</sup>

Detailed rules will be adopted for the implementation of the above requirements.<sup>88</sup>

**Paragraph 2** states that when a company is aware that either the production method or the starting material for a flavouring is significantly different from that included in the risk assessment for its first submission, the company should provide the Commission with all relevant data prior to the marketing of the flavouring.<sup>89</sup>

For the current evaluation of chemically defined flavouring substances, the flavour industry provided data according to Article 3 of Regulation 1565/2000. It is worth noting that Article 3 does not request either the production method or the starting material of

---

<sup>83</sup> See Article 19 of the Regulation

<sup>84</sup> See Article 20 of the Regulation.

<sup>85</sup> See Article 19.1 of the Regulation.

<sup>86</sup> Commission Regulation (EC) No 1565/2000 of 18 July 2000 laying down the measures necessary for the adoption of an evaluation programme in application of Regulation (EC) No 2232/96 of the European Parliament and of the Council, OJ L 180, 19.7.2000, p. 8.

<sup>87</sup> See Article 19.2(last sentence) of the Regulation.

<sup>88</sup> See Article 19.4 of the Regulation.

<sup>89</sup> See Article 19.2 of the Regulation.

the substance, therefore Paragraph 2 of Article 19 of the Regulation is currently not applicable to the flavouring substances on the first Community list. Nevertheless, if a producer has reasons to notify differences and is of the opinion that the new starting material or production method has to be evaluated in order to comply with the conditions set out in Article 4 of this Regulation, the producer has to submit data to the Commission.

According to the Regulation establishing the Common Authorisation Procedure (CAP), EFSA has to draw up implementation guidelines for the evaluation of flavourings within a period of 6 months<sup>90</sup> after the entry into force of this Regulation (means approx. June 2009). Amongst other information requested, starting materials and the production methods might be part of data/information that will be taken into consideration for the evaluation of the flavourings (e.g. flavouring preparations obtained from non food, other flavourings).

**Paragraph 3** urges food business operators to *inform the Commission immediately of any new scientific or technical information which is known and accessible and might affect the assessment of the safety of the flavouring substance.*<sup>91</sup>

## 2. Article 20 – Monitoring and reporting by the Member States

According to **Paragraph 1** *Member States shall establish systems to monitor the consumption and use of flavourings set out in the Community list and the consumption of the substances listed in Annex III<sup>92</sup> on a risk-based approach, and shall report their findings with appropriate frequency to the Commission and to the Authority.*<sup>93</sup>

Member States are given the task to monitor

- the consumption and use of flavourings of the Community List,
- the consumption of the substances as listed in Annex III.

Annex III contains 2 parts:

- The first part (part A) refers to substances which shall not be added as such to food.
- The second part (part B) refers to maximum levels not to be exceeded of certain substances, naturally present in flavourings and food ingredients with flavouring properties, in certain compound food as consumed to which flavourings and/or food ingredients with flavouring properties have been added.

Member States have to work on a risk-based approach and shall report their findings regularly to the Commission and to the Authority.

A common methodology for gathering the information on the two above mentioned subjects shall be adopted after consultation with EFSA and in accordance with the regulatory procedure by 20 January 2011.<sup>94</sup>

---

<sup>90</sup> See Article 9.2 of CAP Regulation (EC) No 1331/2008.

<sup>91</sup> See Article 19.3 of the Regulation.

<sup>92</sup> See Chapter II on Conditions of use of this Guidance Document.

<sup>93</sup> See Article 20.1 of the Regulation.

<sup>94</sup> See Article 20.2 of the Regulation.

## Chapter VI (Articles 30, 24, 10 and 22)

### Transitional and Final Provisions Entry into Force and Application

#### 1. Article 30 – Entry into force and application of the Annexes

The new legislation governing the use of flavourings within the EU is a Regulation which entered into force the 20<sup>th</sup> January 2009.<sup>95</sup>

The date of application of the Regulation is 24 months after its entry into force (i.e. 20 January 2011).<sup>96</sup> Between the date of entry into force and the date of application, the respective national legislations of the Member States will still apply. For “Annex III – substances” (commonly referred to as “Biologically Active Principles” – “BAPs”) this means that the limits stipulated in the previous Directive 88/388/EEC remain valid until the application of the new Regulation. The limitations set for new “BAPs” such as estragole or methyleugenol will only apply as from 20 January 2011.<sup>97</sup>

The Community list of flavourings and source materials (Article 10 of the Regulation) shall apply from the date of application of the Community list.<sup>98</sup> The specific date of application of the Community list is not set in the text.<sup>99</sup>

Annex I will be the so-called Community list containing flavourings and source materials approved for use in and on food. The first part will be a list of permitted flavouring substances. Flavourings and source materials for which an evaluation and approval is required<sup>100</sup> will follow.

Article 27 of the Regulation specifies that the list of flavouring substances shall be adopted at the latest by 31 December 2010. The dates of entry into force and application of this list are not mentioned but provided the list of flavouring substances is published end of 2010, the Community list will apply earliest 18 months later (mid 2012) if no transition period is granted. The date of application might be delayed by the duration of the transition period of the list of flavouring substances.

Definitions in specific legislations on spirit drinks (Regulation (EC) No 110/2008) and aromatized wines (Regulation (EEC) No 1601/91) which need to be adapted to certain new definitions<sup>101</sup> will apply from the date of application of the Community list.<sup>102</sup>

Amendments to Annexes II to V<sup>103</sup> shall apply from the date of entry into force, i.e. 20 January 2009,<sup>104</sup> which means that the Annexes II-V can be amended from that date on, when necessary.

---

<sup>95</sup> See Article 30 Sentence 1 of the Regulation.

<sup>96</sup> See Article 30 Sentence 2 of the Regulation.

<sup>97</sup> See further comments under Section 2. Article 24 – Repeals.

<sup>98</sup> See Article 30 Sentence 3 of this Regulation.

<sup>99</sup> See further comments under Section 3 (Article 10 – Community list of flavourings and source materials).

<sup>100</sup> See Article 9 of the Regulation.

<sup>101</sup> See Article 26 and 28 of the Regulation.

<sup>102</sup> See Article 30 Sentence 4 of the Regulation.

<sup>103</sup> See Article 22 of the Regulation. See further comments under Section 4 (Article 22 – Amendments to Annexes II to V).

<sup>104</sup> See Article 30 Sentence 5 of the Regulation.

Foods lawfully placed on the market or labelled prior to 20 January 2011 which do not comply with this Regulation may be marketed until their date of minimum durability or use-by-date.<sup>105</sup>

The Regulation covers flavourings and certain food ingredients with flavouring properties for use in and on foods. EFFA's interpretation is that this transition period applies to the final foodstuff. 'Placing on the market' means the holding of food or feed for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and other forms of transfer themselves.<sup>106</sup> It does not include the further use of a flavouring (in or on foods). Thus flavourings which do not comply with this Regulation and which are not intended for sale to the final consumer have to be placed on the market well before the date of application of this Regulation.

## 2. Article 24 – Repeals

Directive 88/388/EEC (previous Flavours Directive), Decision 88/389/EEC (establishment of an inventory of the source materials and substances used in the preparation of flavourings) and Directive 91/71/EEC (labelling of flavourings intended for sale to the final consumer) shall be repealed from 20 January 2011.<sup>107</sup>

Directive 88/388 provides maximum levels for commonly referred to as "biologically active principles". As long as it is not repealed, maximum limits set in 88/388/EEC and in respective national legislations still apply. Nevertheless, operators might in principle already be allowed to apply the new maximum levels set in the Regulation due to the direct effect of the entry into force. However, this issue might be treated differently from Member State to Member State.<sup>108</sup> The maximum levels for new substances added to Annex III will only apply 24 months after the entry into force of the Regulation (i.e. 20 January 2011).

Regulation (EC) No 2232/96 (Common procedure for flavouring substances) and further legal acts based on this Regulation like Decision 1999/217 as amended shall be repealed from the date of application of the list of flavouring substances.<sup>109</sup> The date of application is not yet specified. EFFA's interpretation is that it would be mid 2012 if the list of flavouring substances is adopted and published end 2010.

National specific legislations (conditions of use for nature identical and/or artificial flavouring substances) are officially revoked at the date of application of the list of flavouring substances. Member States have the possibility to permit certain substances before this deadline, provided the substances have been evaluated by EFSA and are listed on the Community list. However, the situation might differ amongst the Member States.

References to the repealed acts shall be construed as references to the new Flavour Regulation.<sup>110</sup>

---

<sup>105</sup> See Article 30 Sentence 6 of the Regulation.

<sup>106</sup> See Article 3.8 of Regulation (EC) No 178/2002 ("*General Food Law*").

<sup>107</sup> See Article 24.1 of the Regulation.

<sup>108</sup> In Germany for instance companies should contact the specific "Länder" authority.

<sup>109</sup> See Article 24.2 of the Regulation.

<sup>110</sup> See Article 24.3 of the Regulation.

### 3. Article 10 – Community list of flavourings and source materials

It is EFFA's understanding that any flavouring substance not on the Community list, even if evaluated by JECFA, may not be placed on the market as such and used in or on foods after the application of the Community List and is not permitted in foods that are placed on the market after the application of the Community List.<sup>111</sup>

Regarding flavourings and source materials for which an evaluation and approval is required, EFFA notes that a proposal from EFSA to the Commission concerning the data required for risk assessment of the materials concerned to be submitted is expected mid 2009;<sup>112</sup> consequently, it will be difficult to have such permitted materials listed in a Community list that will initially only contain flavouring substances.

### 4. Article 22 – Amendments to Annexes II to V

*Annexes II to V to this Regulation should be adapted as necessary to scientific and technical progress, taking into account the information provided by producers and users of flavourings and/or resulting from the monitoring and controls by the Member States*<sup>113</sup>.

Amendments to the above mentioned Annexes shall be adopted in accordance with the regulatory procedure with scrutiny<sup>114</sup> as referred to in Article 21(3)<sup>115</sup> of this Regulation.<sup>116</sup>

When, on imperative grounds of urgency, the normal time-limits<sup>117</sup> for the regulatory procedure with scrutiny cannot be complied with, the Commission should be able to apply the urgency procedure provided for in Article 5a(6) of Decision 1999/468/EC for the adoption of amendments to Annexes II to V to this Regulation.<sup>118</sup>

\*\*\*\*\*

18/02/09

<sup>111</sup> See Fn. 98 of this Guidance Document.

<sup>112</sup> See Article 9.2 of Regulation (EC) No 1331/2008 (CAP)

<sup>113</sup> See Recital (32) of the Regulation.

<sup>114</sup> The "regulatory procedure with scrutiny" is one of the legislative procedures embedded in the so-called Comitology system. According to Article 202 ECT the Commission implements the legislative acts adopted by the Council (such as for example the present EC flavourings regulation). In line with the so-called Comitology system established by Decision 1999/468/EC (See OJ L 184, 17.7.1999, p.23 amended by Council Decision 2006/512/EC, of 17 July 2006, OJ L 200, 22.7.2006, p.11) the Commission will be assisted by Committees when implementing the Council's legislative acts. Committees are forums for discussion consisting of representatives from Member States and are chaired by the Commission. They enable the Commission to establish a dialogue with national administrations before adopting implementing measures. So-called "regulatory committees with scrutiny" must allow the Council and the European Parliament (EP) to carry out a check *prior* to the adoption of measures of general scope designed to amend non-essential elements (Please also refer to Recital 30 of the EC flavourings Regulation) of a basic instrument adopted by co-decision. In the event of opposition of either the Council or the EP, the Commission may not adopt the proposed measure, although it may submit an amended proposal or a new proposal.

<sup>115</sup> Article 21.3 of the Regulation refers to Articles 5 a (1) to (4) as well as to Articles 7 and 8 of Decision 1999/468/EC detailing the modus operandi of the regulatory procedure with scrutiny.

<sup>116</sup> See Article 22 and Recital (30) of the Regulation.

<sup>117</sup> The normal time limits are set forth in paragraphs (3), (4) and 5(a) of Decision 1999/468/EC.

<sup>118</sup> See Recital (31) of the Regulation as well as Article 22 referring to Article 21.4 of the Regulation.



EUROPEAN FLAVOUR & FRAGRANCE ASSOCIATION

## EC Regulation on Flavourings

On July 8<sup>th</sup> the European Parliament (EP) voted for the FIAP (Food Improvement Agents Package) compromises including a Regulation on Flavourings. The final regulation of the EP and Council on Flavourings was published on December, 31, 2008.<sup>1</sup> The Regulation will be binding as of January 20, 2011 which is 24 months after its entry into force. During these 24 months transitional period, current national legislation will still be in force.

EFFA welcomes review and updating of the flavourings legislation.

This document summarizes the major changes introduced in the new Regulation; it does not comment on the changes requiring interpretation, which will be included in an EFFA Guidance Document currently under elaboration.

Key issues are:

### Scope

- The title and scope cover flavourings for use in and on foods, certain food ingredients with flavouring properties, food containing flavourings and/or food ingredients with flavouring properties and source materials.

### Definitions

- The general definition of flavourings is to impart or modify odour and/or taste of the foods to which they are added.
- No distinction is made between nature-identical and artificial flavouring substances, both of which will be regarded as “Flavouring substances”.
- Two additional flavouring categories are defined i.e. “flavour precursors” and “other flavourings”.
- Process flavourings are named “Thermal process flavourings”: production conditions and maximum levels for certain substances are set.
- Requirements concerning the processes allowed for natural flavouring substances and flavouring preparations are specified.
- A distinction is established between source materials considered as “food” and “non-food”.

---

<sup>1</sup> REGULATION (EC) No 1334/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC – OJ L 354, 31.12.2008, p. 34.

## Labelling

- Packaging labelling of flavourings for downstream manufacturers and consumers must include details about the presence of food allergens and date of minimum durability.
- Labelling as “natural flavouring substance(s)” may only be used for flavourings where the flavouring part contains exclusively natural flavouring substances.
- Labelling as “natural X flavouring” with reference to the name of the source may only be used if the flavouring component has been obtained exclusively or by at least 95% (w/w) from the cited source, the other maximum 5% (w/w) must also be natural.
- Labelling as “natural X flavouring with other natural flavourings” may only be used when the flavouring component has been partially derived from the cited source and the flavour of the source is easily recognizable.
- Labelling as “natural flavouring” without reference to the name of the source may only be used when a flavour is derived from different source materials and a reference to the source materials would not reflect their flavour or taste.
- Smoke flavourings added to impart smoky flavour to the food must appear in the list of ingredients, either as “smoke flavouring(s)” or with a reference to the source (wood) used for its production.

## Evaluation and authorisation

- **A Community List will be established for:**
  - flavouring substances;
  - other flavourings;
  - flavourings from the following flavouring categories when obtained from non-food sources: thermal process flavourings, flavour precursors, flavouring preparations;
  - source materials other than food;
  - thermal process flavourings for which the production conditions and/or the maximum levels for certain undesirable substances as set out in Annex V are not met.

## Risk management of certain substances

- **The risk management of certain substances naturally present in certain food ingredients with flavouring properties (e.g. herbs, spices) and/or flavourings is based upon the “major contributor approach”:**
  - Maximum levels<sup>2</sup> are established for the presence of these undesirable substances in food which contribute most to the human intake of these substances.
  - Only food ingredients with flavouring properties contributing most to the intake are considered.

---

<sup>2</sup> The maximum levels shall not apply to estragole, methyleugenol and safrole where a compound food contains no added flavourings and the only food ingredients with flavouring properties that have been added are fresh, dried or frozen herbs and spices.

- A general list of substances that should not be added as such to foods is provided in Annex III A.
- Flavouring and foodstuff manufacturers must, at the request of the Commission, **provide information on the consumption and use of flavourings in specific categories of foods.**

### **Regulatory aspects**

- The text is a Regulation and no longer a Directive; this allows a more rapid and harmonized enforcement.
- The introduction of the Comitology procedure – “regulatory procedure with scrutiny” – will lead to a more rapid adaptation of the provisions to technical progress.
- All former standards (national legislation, EU or national codes of practice, other vertical legislation etc.) based upon a differentiation between nature-identical and artificial substances will require amending between the entry into force of the text (January 20, 2009) and its application, 24 months later (January 20, 2011).
- Apart from some exceptions the new EC flavouring Regulation will be binding as of January 20, 2011 which is 24 months after it has come into force. During this period of time Member States must adapt their national legislation.
- The Community List of flavouring substances which will become Annex I of this regulation will have a different publication and application date (see separate EFFA IL 08/01 on the Community List of flavouring substances).

January 6, 2009



EUROPEAN FLAVOUR & FRAGRANCE ASSOCIATION

## Information Letter on the Community List of Flavouring Substances

The Food Improvement Agent Package (incl. the Regulation on Flavourings) has been published on December, 31, 2008. According to Article 27 of the new Regulation on Flavourings, the list of authorized flavouring substances (i.e. the "Community List") will be adopted by end of 2010 at the latest. The list will contain flavouring substances for which the European Food Safety Authority (EFSA) has finished the evaluations and published their opinions.

Currently the safety evaluation by EFSA for some of the substances originally listed on the EU Register<sup>1</sup> as well as for Newly Notified Substances is however still ongoing. For some of these substances EFSA concluded that there is a need for additional information before a final conclusion on them can be reached. EFFA in cooperation with the International Organization of the Flavor Industry (IOFI) is working on a program to collect the requested information for submission to EFSA.

These substances fulfil the general conditions of safe use and most of them have been used by the global flavour industry for many decades. In addition the majority of these substances have already passed a positive safety evaluation by other competent and independent scientific bodies such as JECFA (FAO/WHO Joint Expert Committee on Food Additives) and FEXPAN (FEMA Expert Panel).

As the process of safety evaluation is still ongoing and as long as the Community List has not been published (foreseen at the latest by the end of 2010), it is premature to question what will be either included in or excluded from the Community List. Until its application (expected mid 2012) national legislation in place at the time of adoption of this Regulation continues to apply and flavouring substances complying with these provisions continue to be allowed for use in or on food.

We trust that this information letter will clarify any question on the status and timings of the Community List and provide you with clarity about the continued legality of selling and using existing and newly created flavourings intended for use in the EU marketplace.

18 February 2009

---

<sup>1</sup> COMMISSION DECISION 1999/217/EC adopting a register of flavouring substances used in or on foodstuffs drawn up in application of Regulation (EC) No 2232/96 of the European Parliament and of the Council of 28 October 1996 as amended

### Attachment III: New EU Regulation for flavourings – Examples of labelling (18/02/09)

The listed examples are for clarification purposes and should be read in conjunction with the EFFA Guidance Document (Chapter IV).

#### A. Examples of Natural labelling

##### [Natural flavouring substances – section 5.1]

Flavouring component (only contains natural flavouring substances)	Labelling
<ul style="list-style-type: none"> <li>95% b/w substances derived from mint (e.g. menthol ex arvensis).</li> <li>5% b/w substances derived from orange (e.g. limonene ex orange) which is used to introduce a special note</li> </ul>	'Natural flavouring substances' or 'Natural mint flavouring'
<ul style="list-style-type: none"> <li>94% b/w substances derived from mint (e.g. menthol ex arvensis).</li> <li>6% b/w substances derived from apple (e.g. an acid) which is used to adjust natural variations.</li> </ul>	'Natural flavouring substances' or 'Natural mint flavouring with other natural flavourings'
<ul style="list-style-type: none"> <li>100 % b/w substances derived from apple (e.g. an acid), raspberry (e.g. an ester), orange (e.g. limonene).</li> <li>Apple, raspberry and orange are not recognizable in the overall flavour profile, which is banana</li> </ul>	'Natural flavouring substances" or 'Natural flavouring'

##### [Natural <<X>> flavourings – section 5.2]

Flavouring component (only contains natural flavouring substances and/or flavouring preparations)	Labelling
<ul style="list-style-type: none"> <li>95% b/w derived from mint (e.g. mint oil and/or menthol ex arvensis).</li> <li>5% b/w derived from orange (e.g. orange oil or limonene ex orange) which is used to introduce a special note</li> </ul>	'Natural mint flavouring'
<ul style="list-style-type: none"> <li>97% b/w derived from raspberry (e.g. raspberry distillate and raspberry isolate).</li> <li>3% b/w derived from apple (e.g. an acid) which is used to adjust natural variations.</li> </ul>	'Natural raspberry flavouring'
<ul style="list-style-type: none"> <li>55% b/w derived from orange</li> <li>40% b/w derived from tangerine</li> <li>5% b/w derived from strawberry (e.g. strawberry distillate and/or an aldehyde ex strawberry) which is used to add a special note</li> </ul>	'Natural orange & tangerine flavouring' or 'Natural citrus flavouring'

### Attachment III: New EU Regulation for flavourings – Examples of labelling (18/02/09)

The listed examples are for clarification purposes and should be read in conjunction with the EFFA Guidance Document (Chapter IV).

#### [Natural <<X>> flavourings with other natural flavourings – section 5.3]

Flavouring component (only contains natural flavouring substances and/or flavouring preparations)	Labelling
<ul style="list-style-type: none"> <li>94% b/w derived from mint (e.g. mint oil and/or menthol ex arvensis).</li> <li>6% b/w derived from orange (e.g. orange oil or limonene ex orange) which is used to introduce a special note</li> </ul>	'Natural mint flavouring with other natural flavourings'
<ul style="list-style-type: none"> <li>50% b/w derived from orange</li> <li>40% b/w derived from tangerine</li> <li>10% b/w derived from strawberry (e.g. strawberry distillate and/or an aldehyde ex strawberry) which is used to add a special note</li> </ul>	'Natural orange and tangerine flavouring with other natural flavourings' or 'Natural citrus flavouring with other natural flavourings'

#### [Natural flavouring – section 5.4]

Flavouring component (only contains natural flavouring substances and/or flavouring preparations)	Labelling
<ul style="list-style-type: none"> <li>0% b/w derived from banana</li> <li>100% b/w derived from other sources than banana (e.g. strawberry, raspberry, etc).</li> <li>The overall flavour-profile is 'banana'</li> </ul>	'Natural flavouring'
<ul style="list-style-type: none"> <li>10% b/w derived from banana</li> <li>90% b/w derived from other sources than banana (e.g. strawberry, raspberry, etc).</li> <li>The overall flavour-profile is 'banana' which comes from the other 90% of the source materials.</li> </ul>	'Natural flavouring'

### Attachment III: New EU Regulation for flavourings – Examples of labelling (18/02/09)

The listed examples are for clarification purposes and should be read in conjunction with the EFFA Guidance Document (Chapter IV).

#### B. Examples of Labelling Smoke flavourings

##### [Labelling of Smoke flavourings – section 4]

Flavouring component (contains 'smoke flavourings' as defined in article 3.2.f)	Labelling
<ul style="list-style-type: none"> <li>• 75% b/w flavouring materials other than smoke flavourings (e.g. with flavour profile bacon)</li> <li>• 25% b/w smoke flavourings</li> <li>• the smoke flavourings add a smoky taste to the food</li> </ul>	Flavouring, smoke flavourings or Bacon flavouring, smoke flavourings
<ul style="list-style-type: none"> <li>• 75% b/w natural flavouring substances or flavouring preparations (e.g. with flavour profile bacon)</li> <li>• 25% b/w smoke flavourings</li> <li>• the smoke flavourings add a smoky taste to the food</li> </ul>	Flavouring, smoke flavourings or Bacon flavouring, smoke flavourings <sup>1</sup>
<ul style="list-style-type: none"> <li>• 99.9% b/w flavouring other than smoke flavourings (e.g. with flavour profile coffee)</li> <li>• 0.1% b/w smoke flavourings</li> <li>• the smoke flavourings do not add a smoky taste to the food</li> </ul>	Flavouring or Coffee flavouring

<sup>1</sup> EFFA recommends that the term 'natural' be avoided in combination with the term 'smoke flavourings', since it could mislead the consumer about the naturalness of a product or of the production process (see Whereas (27)).