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GUIDANCE DOCUMENT ON EC REGULATION ON FLAVOURINGS

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* Annex III: This attachment has not been included in this printed version. You can find it here: <http://www.ffa.eu/en/publications/guidance-documents>



General introduction

On 8 July 2008 the European Parliament (EP) voted for the FIAP (Food Improvement Agents Package) which includes a Regulation on Flavourings. The new EC Regulation on Flavourings¹ (hereinafter referred to as the "Regulation") was published on 31 December 2008. The Regulation entered into force on 20 January 2009 and most sections, already have been applicable since 20 January 2011. Since 22 April 2018 the Regulation including Annex I fully applies.

EFFA (European Flavour Association) welcomes this review and the updating of the European flavourings legislation.

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

The current EFFA Guidance Document further elaborates on the changes introduced through the new Regulation and seeks to establish EU wide guidance on the practical application of the new Regulation. It is intended to harmonise the interpretation of the Regulation within the EU Flavour Industry. This guidance aims to 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.² Certain flavourings must, 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.³

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

- | | | |
|----|-------------|---|
| 1. | Chapter I | Subject Matter, Scope and Definitions |
| 2. | Chapter II | Conditions of Use |
| 3. | Chapter III | Union List ⁴ |
| 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.

¹ 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.

² See Chapter I and II of this Guidance Document and also the General Food Law: Regulation (EC) No 178/2002.

³ See Recital (7) of the Regulation.

⁴ This list is still referred to as "Community list" in the Regulation but this name is no longer used. As a consequence of the Lisbon Treaty, the correct reference is "Union List".
Lisbon treaty: <http://eur-lex.europa.eu/JOHtml.do?uri=OJ.C:2007:306:SOM:EN:HTML>

DISCLAIMER

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Attachment I: EFFA Information Letter FL/09/01 on EC Regulation on Flavourings

Chapter I a (Articles 1 and 2)

Subject Matter and Scope

1. Article 1 – Subject Matter of the Regulation

• Extended Scope

Per Article 1 the Regulation lays down rules on 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/EEC⁵ which restricted its scope to flavourings, the Regulation extends its scope to certain food ingredients with flavouring properties.⁶

• Policy objectives

The Regulation aims at achieving 5 complementary policy objectives,⁷ 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), whilst 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"** (now referred to as **"Union list"**) of flavourings and source materials approved for use in and on foods,⁸ (b) a set of **specific conditions of use** for flavourings and food ingredients with flavouring properties in and on foods,⁹ and (c) specific **rules on the labelling** of flavourings.¹⁰

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 list¹¹ of items falling under its scope as well as a list¹² of items to which the Regulation does not apply.

- The Regulation covers:¹³
 - **flavourings** (as defined in Article 3.2 (a) of the Regulation) which are used or intended to be used in or on foods;¹⁴
 - **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.

⁵ See OJ L 184, 15.7.1988, p.61.

⁶ 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 and 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".

⁷ 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 e) protecting the environment.

⁸ See Chapter III of the Regulation (Articles 9–13) and Annex I of the Regulation and Chapter III of this Guidance Document.

⁹ See Chapter II of the Regulation (Articles 4-8) and Chapter II of this Guidance Document.

¹⁰ 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.

¹¹ See Article 2.1 of the Regulation.

¹² See Article 2.2 of the Regulation.

¹³ See also Recital (5) of the Regulation clarifying the scope of the Regulation.

¹⁴ It should be noted that "smoke flavourings" (as defined in Article 3.2 (f) of the Regulation) are also subject to more specific rules laid down in Regulation (EC) No 2065/2003 (See OJ L 309, 26.11.2003, p.1).

- The Regulation does not cover:¹⁵
 - **substances which have exclusively a sweet, sour or salty taste**, such as all sugars, sweeteners, salt (sodium chloride), citric acid;
 - **raw foods**;¹⁶
 - **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.

¹⁵ See also Recital (6) of the Regulation clarifying the scope of the Regulation.

¹⁶ According to Recital (6), “raw foodstuffs” are products not having undergone any processing treatment.



Chapter I (Article 3)

Definitions

1. Introduction

Flavourings are used to impart or modify the odour and/or taste of foods.¹⁷ Flavourings may contain food additives as permitted by Regulation (EC) No 1333/2008¹⁸ and/or other food ingredients incorporated for technological purposes.¹⁹

Flavourings are not intended to be consumed as such.

The general safety obligations/requirements as expressed in Article 4 apply to all flavourings irrespective the category to which they belong. In addition, all flavourings have to comply with the general food law (Regulation (EC) No 178/2002)²⁰.

Flavouring components, as mentioned in Article 16, Article 29 and in Recital (26) 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 containing in their flavouring part solely “natural flavouring substances” as defined in Article 3.2 (c) and/or “flavouring preparations” as defined in Article 3.2 (d) can be labelled with the term “natural”.²¹

With Information Letter **IL FL/10/02** EFFA published the “Guidance Document for the Production of Natural Flavouring Substances and (Natural) Flavouring Preparations in the EU” (See **Attachment II** to this Guidance Document) to bring clarifications that provide a consistent interpretation of what constitutes a natural process under the new Regulation. This Chapter takes into account the recommendations described in this Guidance Document.

2. 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.²² 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 rules²³ apply (See Section 3 below).

Ammonium, sodium, potassium and calcium salts as well as chlorides, carbonates and sulphates are covered by the generic substances, providing that they have flavouring properties.²⁴

¹⁷ See Article 3.2 (a) (i) of the Regulation.

¹⁸ See Regulation (EC) No 1333/2008/EC, OJ L 354, 31.12.2008, p. 16.

¹⁹ See Article 3A of the Regulation.

²⁰ Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

²¹ See Article 16.2 of the Regulation and Chapter IV of this Guidance Document.

²² 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.

²³ See Article 3.2 (c) of the Regulation.

²⁴ See Note 1 to Section 2 of Annex (Union List Part A) to Commission Implementing Regulation adopting the list of flavouring substances (Regulation (EU) No 872/2012).

3. Natural flavouring substance (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".

"Identified in nature" means:

- identified in materials of plant, animal, microbiological, or mineral origin,²⁵

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 the International Organization of the Flavor Industry (IOFI) Information Letter 1333 (*Flavour Fragr. J.*, 2006, **21**: 185), and where necessary in specific guidelines for using the technique of LC-MS for identifications.²⁶

Substances which do not meet the above-mentioned requirements shall not be considered as being 'natural'.

4. Flavouring preparation (Article 3.2 (d))

According to Article 3.2 (d) of 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 or more of the traditional food preparation processes listed in Annex II.²⁷

ISO Standard 9235 gives some examples of different flavouring preparations such as essential oils, extracts and tinctures.²⁸

Article 3.2 (d) makes a distinction between flavouring preparations 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).²⁹

Contrary to the definition under Directive 88/388 Article 3.2 (d) of the Regulation does not include the words "whether concentrated or not".³⁰ EFFA understands that the concentration of the flavouring preparation is thus irrelevant, like under the previous directive.³¹

Due to the way they are produced, flavouring preparations are complex mixtures containing more than volatile flavouring molecules. Therefore the presence of constituents that are naturally occurring in the flavouring preparation due to their presence in the source materials, e.g. intrinsic fruit water, as well as foods / food ingredients used during the manufacturing process, e.g. ethanol, edible oil, acetic acid, can be considered as part of the flavouring preparation.

Flavouring preparations shall be produced in line with appropriate processes as described in Article 3.2 (d) – incl. the traditional processes listed in Annex II – and Article 3.2 (k) taking into account the considerations expressed in Recital (25) and the requirements of Article 4 in order to ensure that consumers are not misled.

If solvents are used for extraction purposes to obtain flavouring preparations, only those listed in the EU Extraction Solvents Directive 2009/32/EC (as amended) shall be used and the applicable maximum residue levels should be observed.³² The remaining amount of extraction solvents depending on the process, together with other intrinsic components from the respective source material e.g., fruit/plant sugars or cell water, are part of the entire flavouring preparation.

It needs to be clearly stipulated that solvents or carriers, added for purposes other than extraction, e.g., for dilution, or standardization, or when used outside the conditions/limitations of EU Directive 2009/32/EC (as amended), will not become part of the entire flavouring preparation.

²⁵ "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 9 of this Chapter).

²⁶ IOFI Working Group on Methods of Analysis (WGMA), *Flavour Fragr. J.* 2010, 25, 2-3.

²⁷ See Article 3.2 (d) of the Regulation. Please also refer to Recital (15) of the Regulation.

²⁸ International Organization for Standardization (ISO): International Standard 9235 – Aromatic natural raw materials – Vocabulary. ISO 1997©.

²⁹ See Article 8 and Article 9 (b) of the Regulation and Chapter III of this Guidance Document

³⁰ See Article 1.2 (c) of Directive 88/388/EEC.

³¹ See also explanation in DG SANCO Working Document WGF/002/02, (2002) which reads as follows: 'flavouring preparation' means a product obtained from materials of vegetable or animal origin, resulting normally in complex flavouring mixtures, e.g. extract of vanillin capsules which contains besides vanillin more than 100 additional substances, many at very low concentrations, or essential oils from citrus fruits, peppermint or spices, or distillates from fruits, vegetables, herbs or spices.

³² Directive 2009/32/EC of 23 April 2009 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients as amended by Directive 2010/59/EU

5. Thermal process flavouring (Article 3.2 (e))

A thermal process flavouring is obtained as a result of intentionally heating a blend of an amino containing ingredient (nitrogen source) and a reducing sugar.

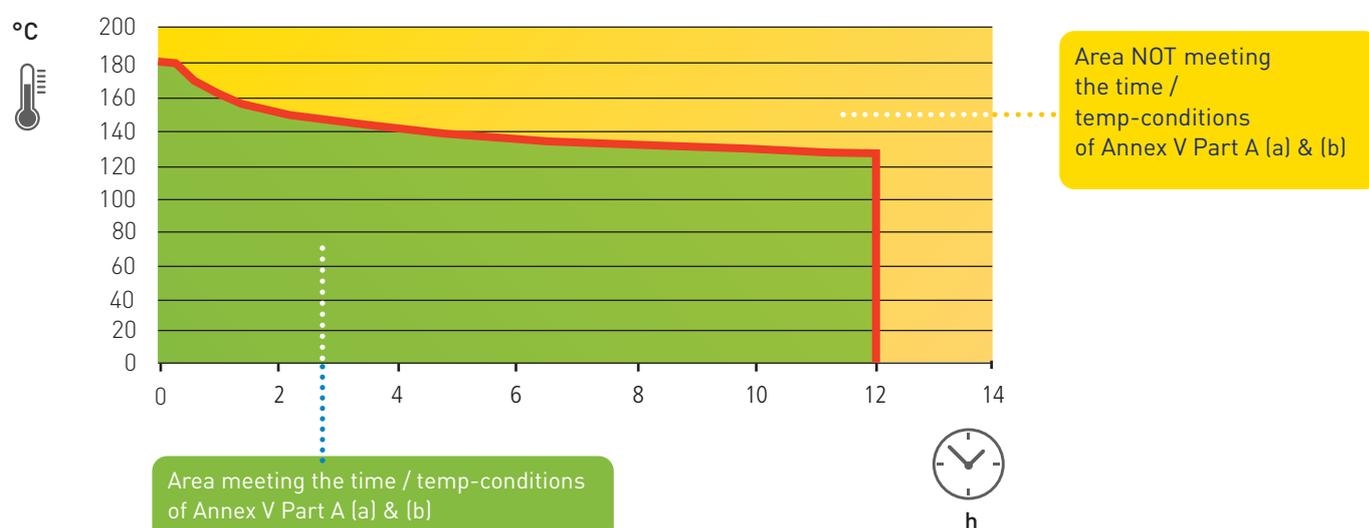
Examples of nitrogen sources include amino acids and their salts, peptides, proteins from foods, hydrolysis products of those proteins. Reducing sugars are e.g. dextrose/glucose, xylose.

The process conditions applied to such mixtures are described 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 for the production as specified in Annex V needs specific evaluation and authorization.³³

As shown in Figure 1 for all Time/Temperature conditions above the red line, the Thermal Process Flavouring has to be evaluated.

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

Figure 1: Time/Temperature Chart for production of Thermal Process Flavourings and differentiation between area *not* meeting the conditions of Annex V Part A versus area meeting those conditions



6. Smoke flavouring (Article 3.2 (f))

Smoke flavourings are regulated by Regulation (EC) No 2065/2003:³⁴

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';
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.

³³ See Article 9 (c) of the Regulation.

³⁴ OJ L 309, 26.11.2003, p. 1.

According to Article 6 of the above mentioned 'Smoke Flavourings Regulation' a list of the primary products authorised to the exclusion of all others in the Community for use as such in or on foods and/or for the production of derived smoke flavourings shall be established. In 2013 the **'Union List of authorised smoke flavouring primary products'** was established by **Commission Implementing Regulation (EU) No 1321/2013**³⁵. The regulation entered into force on 1 January 2014 [see EFFA IL 13/23]³⁶.

In 2014 EFFA issued its Guidance Document on the Proportional Reduction of Smoke Flavouring Primary Products (this includes a calculation tool) [see EFFA IL 14/02³⁷ & EFFA Guidance Document 14/01³⁸]

7. 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.

Precursors can be single substances or mixtures. Some flavour precursors can belong to more than one flavouring category depending on their intended use: for example some amino acids can be used as flavour precursors but if they are listed on the UL of Flavouring Substances (Part A of UL), they may also be used for this purpose.

8. 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.³⁹ As mentioned in the Introduction flavourings containing in their flavouring part "other flavourings" can never be labelled with the term "natural".

Rum ether is regarded as an example of a product which falls into the category of "other flavourings".

9. 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.⁴⁰

According to Regulation 178/2002/EC⁴¹, food is considered as any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans⁴² 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.⁴³ This is considered to take account of materials used anywhere worldwide⁴⁴ for these purposes prior to the date of application of the Regulation.⁴⁵

³⁵ Commission Implementing Regulation (EU) No 1321/2013 of 10 December 2013 establishing the Union list of authorised smoke flavouring primary products for use as such in or on foods and/or for the production of derived smoke flavourings – OJ L 333, 12.12.2013, p. 54

³⁶ EFFA IL 13/23 - Publication of the Union List of Authorised Smoke Flavouring Primary Products – 13.12.2013

³⁷ EFFA IL 14/02 - EFFA Guidance Document with Calculation Tool for the Proportional Reduction of Smoke Flavouring Primary Products – 10.03.2014

³⁸ EFFA Guidance Document 14/01 - EFFA Calculation Tool for the Proportional Reduction of Smoke Flavouring Primary Products – 10.03.2014

³⁹ See Article 9 (e) of the Regulation and Chapter III of this Guidance Document.

⁴⁰ See Article 3.2 (j) of the Regulation.

⁴¹ See Article 2 of Regulation (EC) No 178/2002 ("General Food Law") OJ L 31, 1.2.2002, p. 1.

⁴² 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, Tyōzaburō, Tanaka Keigaku Publishing co, Tokyo, 1976.

⁴³ See Article 3.3 of the Regulation. Please also refer to Recital (16) of the Regulation.

⁴⁴ No restriction is made in the Regulation limiting this only to the European Union.

⁴⁵ The 20 January 2011 is the date of application of the Regulation.

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.⁴⁶

Source materials listed in Part A of Annex IV⁴⁷ 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.⁴⁸

10. Flavourings with modifying properties (FMPs)

According to the Definition in Article 3.2 (a) flavourings can either **impart** odour and/or taste to food or **modify** odour and/or taste of food.

The term “flavouring with modifying properties” has not been defined in the Regulation but can be interpreted to mean those flavourings which modify odour and/or taste of the food.

The European Commission issued “Guidance notes on the classification of a flavouring substance with modifying properties and a flavour enhancer” on 27 May 2014. [**Attachment IX**]. The Commission Guidance Note aims at providing food business operators and competent authorities with criteria in order to distinguish between the use of a chemically defined substance as a flavour enhancer or as a flavouring substance with modifying properties.

EFFA has issued a dedicated Guidance Document on Flavourings with Modifying Properties in March 2015 aiming at providing supplemental guidance to the flavouring industry and to the food industry on how to establish the appropriate use of flavourings with modifying properties. [**Attachment X**]



Attachment IIa: EFFA Information Letter FL/10/02 on the EFFA Guidance Document for the Production of Natural Flavourings

Attachment IX: Commission Guidance notes on the classification of a flavouring substance with modifying properties and a flavour enhancer

Attachment X: EFFA Guidance on Flavourings with Modifying Properties (FMPs)

⁴⁶ See Article 9 of the Regulation.

⁴⁷ Tetraploid form of *Acorus calamus* L.

⁴⁸ 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)⁴⁹ have expressed respective opinions on a number of substances occurring naturally in source materials for flavourings and food ingredients with flavouring properties, e.g. some herbs, spices. According to the Committee of Experts on Flavouring Substances of the Council of Europe (CoE)^{50, 51}, these substances may raise toxicological concern. Although these substances have in the past commonly been referred to within the food industry as “Biologically Active Principles” (so-called “BAPs”) they will be referred to as “Restricted Substances” (RS) in this Guidance Document. The Regulation uses the undefined term “certain substances”.

2. The new Regulation

With reference to the Regulation, substances for which toxicological concern was confirmed by SCF/EFSA should be regarded as naturally occurring undesirable substances which should not be added as such to food.⁵² Due to their natural occurrence, these substances might be present in flavourings and certain food ingredients with flavouring properties.⁵³

2.1. Scope⁵⁴

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.⁵¹

Consequently Annex III part B of the Regulation refers to maximum levels of “RS”, 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.

⁴⁹ Panel on Food Additives, Flavourings, Processing aids and Flavourings and Materials in Contact with Food (AFC) and since July 2008 the EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF)

⁵⁰ 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.

⁵¹ 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.

⁵² See Recital (8) of the Regulation.

⁵³ See Recital (9) of the Regulation.

⁵⁴ See also Chapter 1a of this Guidance Document under Scope.

⁵⁵ 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.⁵⁶

Products (flavourings and/or food) which do not comply with this Regulation are prohibited.⁵⁷

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

A list of 15 substances which should not be added as such to foods (including flavourings and food ingredients with flavouring properties) is provided in Annex III part A (those substances which are also subject to maximum levels in Annex III part B are indicated in bold – see 2.2.3).⁵⁸

- Agaric acid
- Aloin
- **Beta-asarone**
- Capsaicin (new)
- **Coumarin**
- **Estragole** (new)
- **Hydrocyanic acid**
- Hypericine
- **Menthofuran** (new)
- **Methyleugenol** (new)
- **Pulegone**
- **Quassin**
- **Safrole**⁵⁹
- **Teucrin A** (new)
- **Thujone (alpha and beta)**.

According to the first principle of HACCP (Hazard Analysis and Critical Control Point) as laid down in Regulation 852/2004/EC,⁶⁰ 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.

Substances which are not listed in Annex III part B as well and hence which are not subject to maximum levels in specified applications, are not regarded as a hazard. Therefore their potential presence in flavourings and/or their source materials is usually not controlled on a routine basis by flavour manufacturers.



RECOMMENDATION

Flavour producers commit themselves to control the potential presence of ANNEX III A substances in flavourings in case these substances are also listed in Annex III part B and hence subject to maximum limits in specified applications.

In the Quality Assurance System of flavour producers, these substances should be identified.

⁵⁶ See Article 4 of the Regulation.

⁵⁷ See Article 5 of the Regulation.

⁵⁸ *Nota bene: Berberin and santonin are no longer mentioned in this list.*

⁵⁹ 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).*

⁶⁰ 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 levels⁶¹ 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.⁶²

- Maximum levels for certain naturally occurring undesirable substances should focus on the food or food categories which contribute most to dietary intake.⁶³
- Only food ingredients with flavouring properties contributing significantly to the presence in food of certain naturally occurring undesirable substances are considered.⁶⁴

For those foodstuffs not listed in this Annex, the general rules for safety apply.⁶⁵

Annex III part B sets maximum levels for the following 11 substances:⁶⁶

- Beta-Asarone
- Coumarin
- Estragole (new)
- Hydrocyanic acid
- Menthofuran (new)
- Methyleneugenol (new)
- Pulegone
- Quassin
- Safrole⁶⁹
- Teucrin A (new)
- Thujone (alpha & 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.⁶⁷



RECOMMENDATION

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

2.2.4 Monitoring and Reporting by Member States⁶⁸

Member States shall establish systems to monitor the consumption of “RS” 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 had to be adopted by 20 January 2011 (Working Document not yet available).⁶⁹

⁶¹ The maximum levels shall not apply to estragole, methyleneugenol 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; however, other flavourings which do not contribute to the presence of these three substances may be used (Letter from the European Commission to ESA of 16 March 2009).

⁶² See Recital (9) of the Regulation.

⁶³ See Recital (10) of the Regulation.

⁶⁴ See Article 3.2 (i) of the Regulation.

⁶⁵ See Article 14 of EC Regulation 178/2002 – EC Basis Regulation on Food Law.

⁶⁶ 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.

⁶⁷ See Article 6.2 of the Regulation.

⁶⁸ See also Chapter V of this Guidance Document (Monitoring).

⁶⁹ See Article 20 of the Regulation.



RECOMMENDATION

Flavour producers commit themselves to communicate to the Commission and Member States respectively all relevant data as 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, micro-biological or mineral materials raising concern for human health in the production of flavourings and food ingredients with flavouring properties and their application in food production.⁷⁰

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.⁷¹ For the time being there is only one source material listed: Tetraploid form of *Acorus calamus L.*⁷²



RECOMMENDATION

Flavour producers should ask for confirmation about the absence of tetraploid form of *Acorus calamus L.* in calamus oil. The “Restricted Substance” in calamus oil is beta-asarone.

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.⁷³ These source materials are (common names):

Quassia	For beverages and bakery wares (the limits for quassin still apply)
White agaric mushroom	For alcoholic beverages
St. John's wort	For alcoholic beverages
Wall germander	For alcoholic beverages (the limits for teucriin A still apply)

2.2.6 Recommended analytical methods/criteria

IOFI's Working Group on Methods of Analysis (WGMA) 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 group⁷⁴ for which a satisfactory validation study was performed for safrole and pulegone.

In addition, a decision was adopted within the WGMA in 2002 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.

⁷⁰ See Recital (11) of the Regulation.

⁷¹ See Article 7.1 of the Regulation.

⁷² Article 22 allows amendments to Annexes II to V (see Chapter VI of this EFTA Guidance).

⁷³ See Article 7.2 of the Regulation.

⁷⁴ IOFI (WGMA), Z. Lebensm. Unters. Forsch., 186, 36-38 (1988).

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)⁷⁵, 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.^{76, 77} 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.⁷⁸ This methodology for the Annex III restricted substances has undergone evaluation in several flavouring-industry laboratories, and the final version of an IOFI Recommended Method for GC-MS determination of Restricted Substances in flavourings and raw materials has been published recently⁷⁹.

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,^{80, 81, 82, 83} and will be evaluated by the WGMA in the near future.

⁷⁵ IOFI (WGMA), *Flavour Fragr. J.* 2012, 27, 224–226

⁷⁶ Salagoity et al., *Ann. Falsif. Exp. Chim. Tox.*, 95 (958), 71-77 (2002).

⁷⁷ Scotter et al., http://www.foodbase.org.uk/admintools/reportdocuments/528-1-1227_A01067_Annex_III_Cyanogens_SOPx.pdf

⁷⁸ Bassereau et al., *J. Agric. Food Chem.*, 55, 25-31 (2007).

⁷⁹ IOFI (WGMA), *Flavour Fragr. J.* 2015, 30, 160-164

⁸⁰ Vitanyi et al., *Rapid communications in Mass Spectrometry*, 11, 691-693 (1997).

⁸¹ Basisio et al., *Food Additives and Contaminants*, 21 (5), 407-414 (2004).

⁸² Lander et al., *Z. Lebensm. Unters. Forsch.*, 190, 410-413 (1990)

⁸³ Scotter et al., http://www.foodbase.org.uk/admintools/reportdocuments/528-1-1226_A01067_Annex_II_Coumarin_SOPx.pdf



Chapter III (Articles 9-12)

Union List

This Chapter relates to the **Union List of Flavourings and Source Materials Approved for Use in or on Foods**.⁸⁴

In the Regulation this list is still referred to as “**Community List**” but this name is no longer used. As a consequence of the Lisbon Treaty,⁸⁵ the correct reference is “**Union List**”.

Chapter III lays down the provisions for the inclusion of flavourings and source materials approved for use in or on foods in the Union List and defines for which flavourings and source materials an approval is required.

The Union List of flavourings and source materials approved for use in and on foods is being added to Annex I of the Regulation in a stepwise approach. The first stage was the introduction of the List of flavouring substances (Part A of the Union List) through Implementing Regulation (EU) No 872/2012⁸⁶ often referred to as the “Union List of Flavouring Substances”.

> The next step is the population since April 22, 2018 of those annexes (Part B to F) with flavouring ingredients for which an evaluation and approval is needed according to **Article 9**:

- Flavouring substances (Part A),
- Flavouring preparations obtained from non-food source materials (Part B),
- 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 (Part C),
- Flavour precursors obtained from source materials other than food (Part D),
- Other flavourings (Part E),
- Source materials other than food (Part F).

It should be noted though that up to now only applications have been submitted for a few examples of “other flavourings” whereas no applications have been submitted for the categories for Parts B, C, D & F hence EFFA has been informed by the Commission that the Union List Parts B, C, D & F will remain empty.

For more information regarding the definitions of these flavourings and source materials please refer to Chapter I of this Guidance Document (Definitions).

> **Article 10** of the Regulation provides for the legal implications of the Union List (Article 10 of the Regulation still refers to the “**Community List**”).

Only those flavourings and source materials subject to Article 9 which are included in the Union list may be placed on the market as such and used in or on foods.

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

⁸⁴ See Articles 9-12 as well as Annex I of the Regulation.

⁸⁵ See General Introduction and reference to Lisbon Treaty (Footnote 4).

⁸⁶ Commission Implementing Regulation (EU) No 872/2012 adopting the list of flavouring substances provided for by Regulation (EC) No 2232/96, [...] introducing it in Annex I to Regulation (EC) No 1334/2008 (OJ L 267/1, 2.10.2012)

> **Article 11** of the Regulation refers to the conditions for inclusion of flavourings and source materials in the Union 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 Union list has to be done in accordance with the “Common Authorisation Procedure” (CAP) as laid down in Regulation (EC) No 1331/2008.⁸⁷

The 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.⁸⁸

The implementing measures for CAP defining the format and content of an application and data required for the risk assessment of the substances concerned have been established and published in the Official Journal: Commission Regulation (EU) No 234/2011 implementing Regulation (EC) No 1331/2008.⁸⁹

The implementing measures apply since 11 September 2011. For the submission of a dossier of a new flavouring (flavouring substance or any flavouring and source material covered by Article 9 (b)-(f)) the EFSA Guidance on the data required for the risk assessment of flavourings to be used in or on foods has to be followed. This Guidance Document (EFSA scientific opinion) has been published in the EFSA Journal 2010; 8(6):1623.

For that purpose the Commission has issued a *Practical guidance for applicants on the submission of applications on food additives, food enzymes and food flavourings*.⁹⁰

> **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.⁹¹

Flavourings which are already listed on the Union 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 Regulation (EC) No 1829/2003.

For additional information regarding this **Union List** please refer to the EFFA **Information Letter IL FL/12/07** (See **Attachment III** to this Guidance Document).



Attachment III: EFFA Information Letter FL/12/07 on the Publication of the Union List

⁸⁷ 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.

⁸⁸ See Article 1.1 of Regulation 1331/2008/EC (CAP).

⁸⁹ OJ L 64, 11.3.2011, p. 15.

⁹⁰ See : http://ec.europa.eu/food/food/faef/authorisation_application_en.htm

⁹¹ 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 include the 'sales description' and are similar to those laid down in Directive 88/388/EEC⁹² with three additions. These require that *a date of minimum durability or use-by-date and allergen information according to the food labelling Directive⁹³ as amended*, and, if necessary, *the special conditions for storage and/or use* have 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.

Additional note on Article 15.1 (g):

In particular Article 15.1 (g) stipulates the following:

(g) *an indication of the maximum quantity of each component or group of components subject to quantitative limitation in food and/or appropriate information in clear and easily understandable terms enabling the purchaser to comply with this Regulation or other relevant Community law;*

To comply with the requirements laid down in Article 15.1 (g), the following has to be taken into account:

- (a) "Restricted substances" as listed in Annex III Part B of the present Regulation EC (No) 1334/2008 (see Chapter II of this Guidance Document for further information)
- (b) "Primary products" defined as primary smoke condensates and primary tar fractions as laid down in Article 3 of the Regulation (EC) No 2065/2003 on smoke flavourings; in the case of a derived smoke flavouring as defined in Article 3, the quantitative relation to the primary product has to be given according to Article 13 of the Regulation (EC) No 2065/2003. The identifying code and the quantity have to be provided since the List of authorized primary products applies.

⁹² Council Directive 88/388/EEC 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.

⁹³ 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.

- (c) Caffeine and quinine as laid down in Directive 2002/67/EC [*which has been repealed as from 13 December 2014 and replaced by Regulation (EU) No 1169/2011*⁹⁴] on the labelling of foodstuffs containing quinine, and of foodstuffs containing caffeine
- (d) Glycyrrhizic acid as mentioned in Directive 2004/77/EC on the labelling of certain foods containing glycyrrhizic acid and its ammonium salts
- (e) Additives as laid down the Regulation EC (No) 1333/2008

Multifunctional substances can be used for flavouring purposes (flavouring substances) or for technological purposes (additives). For these substances the declaration should be done according to the following:

- (a) If the substance is used for its **flavouring properties**, and if no restriction has been laid down in Part A of the Union List, no quantitative disclosure is provided.
- (b) If the substance is used for its **flavouring properties** and if a restriction of use has been laid down in Annex I of the Regulation EC (No) 1334/2008, either the quantitative disclosure of the substance will be provided, or otherwise appropriate information in clear and easily understandable terms.
- (c) If the substance is known to be **restricted from all sources** (i.e. benzyl alcohol), the substance has to be quantitatively disclosed from all its sources regardless whether it is used as a flavouring substance or as an additive.
- (d) If the substance is used as an additive for which restrictions have been laid down, the quantitative disclosure will be provided.

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.⁹⁵ In case of uncertainty it is recommended to consult the flavour supplier for additional information or help.

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. However, the assessment of the sensorial properties that determine the labelling in the final product (i.e. designation in the list of ingredients) has to be done by the food manufacturer. The labelling of the flavouring provided by the flavour industry (sales description) is a helpful indication. At all cases the denomination 'flavouring' will be suitable (see Paragraph 3 below).

2.3.1. Labelling of smoke flavourings

When flavouring materials are used that are defined as 'smoke flavourings' and at the same time add a smoky taste to the final food (Article 29), 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 list of the final food. An example of the last category is 'smoke flavouring produced from beech'. The assessment of the sensorial properties that determine whether 'smoke flavourings' appear in the labelling of the final product (i.e. designation in the list of ingredients) has to be done by the food manufacturer.

EFFA reiterates that the term 'natural' should 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 recital (27)).

⁹⁴ Regulation (EU) No 1169/2011 on the provision of food information to consumers – OJ L 304, 22.11.2011, p. 18

⁹⁵ See Regulation (EU) No 1169/2011 on the provision of food information to consumers, Art. 8.2 & 8.8

3. Labelling of flavourings

'Flavourings' or 'a more specific name or description of the flavouring', continue to be authorised terms (see Article 15). 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' (i.e. mentioning the name of Essential oils and extracts), and others, remain authorised.

3.1. Natural labelling

The overall condition that needs to be met is that the flavouring component⁹⁶ 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.⁹⁷

3.1.1. 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 <<X⁹⁸>> flavourings*', '*natural <<X>> flavouring with other natural flavourings*' or '*natural flavouring*' may be used as an alternative.

3.1.2. 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 be obtained at least 95% by w/w from the source material referred to and the flavour perception of the named source needs to be easily recognized.⁹⁹

• Compositional Assessment

The 95/5-ratio is examined on the basis of the formula composition. At least 95% by w/w of the flavouring component (i.e. flavouring preparations and/or natural flavouring substances as defined under Article 3 of the Regulation) have to be obtained from the source material(s) referred to.

⁹⁶ 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'.

⁹⁷ See Article 15.1 (a) of the Regulation.

⁹⁸ <<X>> stands for <<food(s) or food category or source(s)>>.

⁹⁹ 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.

The wording of the Regulation indicates that when considering a “flavouring preparation” – as part of the “flavouring component” of a given “natural <<X>> flavouring” – in the quantitative determination pursuant to Art. 16.4, the entire “flavouring preparation”¹⁰⁰ has to be taken into account. This interpretation has been confirmed by the competent EU Commission Services¹⁰¹ and the broad majority of the Members of the Standing Committee on the Food Chain and Animal Health (SCoFAH).¹⁰²

• Sensorial Assessment

The sensorial properties are evaluated by an expert panel¹⁰³. The (min.) 95 % part and the (max.) 5 % part are – according to the intended application – placed in the best suited test medium: (i) sugar water, (ii) sugar + citric acid water, (iii) drinking water (if necessary demineralized), (iv) edible oil or (v) salt water.

Both parts are neutrally tasted by a suitable expert panel using defined flavour descriptors (as, for instance, strawberry, jammy, green, ripe etc).

Recital (26) of the Regulation refers to the other 5% of the flavouring component (from other sources). 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. Examples provided are a more fresh, pungent, ripe or green note and/or to modify the flavour profile. However, the 5% part may not reproduce the total flavour profile of the 95% part from the source material referred to; otherwise the flavouring does not meet the provisions of Article 16.4. (See Attachment VI: “Flavour Wheels”)

• Natural <<X and Y>> flavouring

It is possible to label flavourings as ‘*natural <<X and Y>> flavouring*’ when the total source material from the named sources is at least 95% by w/w of the flavouring component. The flavour perception of the named sources needs to be easily recognised¹⁰⁰. In line with the labelling requirements, the major contributor by weight needs to be mentioned first. In general it is recommended to refer to two sources as a maximum.

3.1.3. 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 present¹⁰⁴ and that their flavour can easily be recognised⁹⁹. 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*’ (see Article 16.6).

• 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 recognised⁹⁹. In line with the labelling requirements, the major contributor by weight needs to be mentioned first. In general it is recommended to refer to two sources as a maximum.

¹⁰⁰ See Chapter 1, Sub-Section 4.

¹⁰¹ NOTE TO THE STANDING COMMITTEE ON FOOD CHAIN AND ANIMAL HEALTH, TOXICOLOGY SECTION; Brussels 22. January 2013; European Commission, Health and Consumers Directorate - General, Safety of the Food Chain

¹⁰² SUMMARY REPORT OF THE STANDING COMMITTEE ON THE FOOD CHAIN AND ANIMAL HEALTH, held in Brussels on 31. January 2013, (Section Toxicological Safety of the Food chain); European Commission, Health and Consumers Directorate -General; Brussels SANCO E (2013) 165520

¹⁰³ The assessment should be done based on evolving and established methodologies using applicable ISO standards as a minimum requirement

¹⁰⁴ Recital (26) mentions an upper limit in the flavouring component of less than 95% by weight. A minimum limit is not provided.

3.1.4. 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*’.

It is EFFA's understanding that in case one source material is used the same principle can be adhered to.



GENERAL NOTE

Examples of labelling flavourings are given in the Attachment IV and a Flow Chart is given for additional guidance in Attachment V.



Attachment IV: Examples of labelling of flavourings

Attachment V: Flow chart for labelling of flavourings (03/09/2010)

Attachment VI: Flavour wheels “NATURAL <X> FLAVOURING”



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 operators¹⁰⁵ and by the Member States.¹⁰⁶ 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.¹⁰⁷ 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 1565/2000.¹⁰⁸ This information shall be made available to Member States by the Commission.¹⁰⁹

Detailed rules will be adopted for the implementation of the above requirements.¹¹⁰

> **Paragraph 2** states that when a company is aware that either the production method or the starting material for a flavouring, already approved under the Regulation, 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 to allow an evaluation of the flavouring to be undertaken by the authority with regard to the modified production or characteristics.¹¹¹

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 the substance, therefore Paragraph 2 of Article 19 of the Regulation is currently not applicable to the flavouring substances on Part A of the Union list, except for newly notified substances under the Common Authorisation Procedure (CAP) whereby more details on the production process have to be given.¹¹²

¹⁰⁵ See Article 19 of the Regulation.

¹⁰⁶ See Article 20 of the Regulation.

¹⁰⁷ See Article 19.1 of the Regulation.

¹⁰⁸ 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.

¹⁰⁹ See Article 19.1 (last sentence) of the Regulation.

¹¹⁰ See Article 19.4 of the Regulation.

¹¹¹ See Article 19.2 of the Regulation.

¹¹² See Annex (Union List Part A) to Implementing Regulation (EU) No 872/2012 adopting the list of flavouring substances (OJ L 267/1).

In addition, 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.

Following a request from the Commission, the Scientific Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (EFSA CEF Panel) was asked to provide scientific advice regarding the data required for the evaluation of flavourings. This Guidance Document has been published in the EFSA Journal 2010; 8(6):1623.

On the basis of this scientific advice, the Commission has established and published implementing measures (see Ch III).⁸⁹

> **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.*¹¹³

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 Union List and the consumption of the substances listed in Annex III*¹¹⁴ *on a risk-based approach, and shall report their findings with appropriate frequency to the Commission and to the Authority.*¹¹⁵

Member States are given the task to monitor

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

Annex III contains 2 parts (see also Chapter II):

- 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 had to be adopted after consultation with EFSA and in accordance with the regulatory procedure by 20 January 2011 (Commission Working Document under discussion with Member States).¹¹⁶

¹¹³ See Article 19.3 of the Regulation.

¹¹⁴ See Chapter II on Conditions of use of this Guidance Document.

¹¹⁵ See Article 20.1 of the Regulation.

¹¹⁶ 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

1.1 Paragraph 1 and 2 of Article 30

The Regulation on flavourings entered into force on 20 January 2009 and applies since 20 January 2011.¹¹⁷

1.2. Paragraph 3 of Article 30

Article 10 of the Regulation stipulates that only those flavouring substances included in the "Community List" (now 'Union List') may be placed on the market. The Union List of flavouring substances was established by Implementing Regulation (EU) No 872/2012 which entered into force on 22nd October 2012 and applied from 22nd April 2013. Regulation 872/2012 resulted in the introduction of a list of substances into Annex I Part A of the Regulation on flavourings.

The application date of Article 10 was 18 months after the date of application of the Union List Part A i.e. 22nd October 2014.

After that date only those flavouring substances which are included in Part A of the Union List may be placed on the market as such and used in or on foods under the conditions of use specified therein, where applicable.¹¹⁸

1.3. Paragraph 4 of Article 30

Amendments to legislation on spirit drinks (Regulation (EC) No 110/2008) and aromatized wines (Regulation (EEC) No 1601/91) applied from the date of application of the Union List, i.e. from 22nd April 2013.¹¹⁹

¹¹⁷ See Article 30 Paragraph 1 of the Regulation.

¹¹⁸ See Article 9 and 10 of this Regulation.

¹¹⁹ See Article 30 Sentence 4 of the Regulation and Article 5 of the Commission Regulation (EU) No 873/2012 on transitional measures concerning the Union list of flavourings and source materials (OJ L 267/162).

1.4. Paragraph 5 of Article 30

Foods lawfully placed on the market or labelled prior to 20 January 2011 which do not comply with the Regulation may be marketed until their date of minimum durability or use-by-date.¹²⁰

'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.¹²¹

2. Article 24 – Repeals

1. Directive 88/388/EEC (EC 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) were repealed on 20 January 2011.¹²²
2. Regulation (EC) No 2232/96 (Common procedure for flavouring substances) and Regulation (EC) No 1565/2000 (adoption of evaluation program) were repealed from the date of application of the "List of flavouring substances"¹²³, i.e. on 22nd April 2013 but will continue to apply to "flavouring substances under evaluation" pending their inclusion as evaluated substances in Part A of the UL or their removal from that list.¹²⁴ Decision No 1999/217 (Register of flavouring substances) was repealed with effect from 22 April 2013.¹²⁵ National specific legislations (conditions of use for "nature identical" and/or "artificial" flavouring substances) were officially revoked at the date of application of the "Union List of flavouring substances".
3. References to the repealed acts shall be construed as references to the new Regulation.¹²⁶

3. Article 10 – Union List of flavourings and source materials

Flavouring substances *not* on Part A of the Union list, may *not* be placed on the market as such and used in or on foods *after* the application date of Article 10 (i.e. 22 October 2014) (see 1.2 above).

Regarding flavourings and source materials for which an evaluation and approval is required, (as mentioned under Chapter V) EFSA adopted Guidance on the data required for the risk assessment of flavourings to be used in or on foods. This Guidance Document (EFSA scientific opinion) has been published in the EFSA Journal 2010; 8(6):1623.

- Part A of this Guidance provides a proposal concerning the data required for the risk assessment of flavouring substances, i.e. chemically defined substances with flavouring properties.
- Part B of this Guidance provides a proposal concerning the data required for the risk assessment of categories of flavourings other than flavouring substances for which an evaluation and an approval is required according to Article 9 (b) – (f) of the Regulation.

On the basis of this scientific opinion, the Commission has established and published implementing measures (see Ch III).⁸⁹

¹²⁰ See Article 30 Sentence 6 of the Regulation.

¹²¹ See Article 3.8 of Regulation (EC) No 178/2002 ("General Food Law").

¹²² See Article 24.1 of the Regulation.

¹²³ See Article 24.2 of the Regulation.

¹²⁴ See Art. 6 & 7 of Commission Implementing Regulation (EU) No 872/2012.

¹²⁵ See Art. 8 of Commission Implementing Regulation (EU) No 872/2012.

¹²⁶ See Article 24.3 of the Regulation.

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.¹²⁷

Amendments to the above mentioned Annexes shall be adopted in accordance with the regulatory procedure with scrutiny¹²⁸ as referred to in Article 21(3)¹²⁹ of this Regulation.¹³⁰

When, on imperative grounds of urgency, the normal time-limits¹³¹ 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.¹³²

EFFA notes that Regulation (EU) No 182/2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers entered into force on 1st of March 2011.¹³³ The transition provisions stipulated in Article 13 of the above mentioned regulation should be observed.



Attachment VII: Information Letter IL/13/03 on Time Lines & Transitional Periods of the Union List

Attachment VIII: Time Line Charts of the Union List

First version, 18/02/09

Revised version (V2.0), 03/09/10

2nd Revised version (V3.0), 11/03/13

3rd Revised version (V4.0), 30/06/15

4th Revised version (V5.0), 29/02/16

5th Revised version (V6.0), 05/04/18

¹²⁷ See Recital (32) of the Regulation.

¹²⁸ 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.

¹²⁹ 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.

¹³⁰ See Article 22 and Recital (30) of the Regulation.

¹³¹ The normal time limits are set forth in paragraphs (3), (4) and 5(a) of Decision 1999/468/EC.

¹³² See Recital (31) of the Regulation as well as Article 22 referring to Article 21A of the Regulation.

¹³³ See Regulation (EU) No 182/2011 (OJ L 55/13, 28.2.2011)



Attachments



ATTACHMENT I

EFFA Information Letter FL/09/01 on EC Regulation on Flavourings

On July 8th 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, 2008.¹ 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.

The European Flavour Association (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".

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.

¹ 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.

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 levels² 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.
- 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 EFA IL 08/01 on the Community List of flavouring substances).

January 6, 2009

² 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.



ATTACHMENT IIa

EFFA Information Letter FL/10/02 on the EFFA Guidance Document for the Production of Natural Flavourings

EFFA (European Flavour Association) has finalised its Guidance Document for the Production of Natural Flavouring Substances and (Natural) Flavouring Preparations (herein abbreviated “Natural Flavouring Ingredients”) in the EU.

This Guidance Document is a follow-up to the previous Guidance Document on the new European legislation on flavourings (Regulation (EC) No 1334/2008) which was issued with EFFA Information Letter FL/09/02 of 19/02/2009.

Whereas the previous Guidance Document of 2009 mainly focused on the practical application of the Flavouring Regulation and highlighted the major changes compared to the current Flavouring Directive 88/388/EEC, the purpose of the current document is to provide a consistent interpretation of what constitutes a permissible process for the manufacture of Natural Flavouring Ingredients in light of the new Flavouring Regulation.

This interpretation:

- is ready to serve as a European Flavour Industry proactive proposition on the interpretation of Article 3.2 (c, d, k) and Annex II of Regulation (EC) No 1334/2008, while taking into account the scope of Recital (25),
- serves as a platform for the European (EFFA) Flavour Industry self-policing (for the distribution or sale or use of natural flavouring substances and flavouring preparations),
- constitutes the Guidance Document that should be taken as a basis for an EFFA Code of Practice on this subject,
- serves as a platform for explaining the same topic with other stakeholders within the EU and with IOFI.

This Guidance Document consists of six Chapters outlining:

- General principles;
- Traditional food preparation processes;
- Appropriate physical processes;
- Microbiological and enzymatic processes;
- Processes used in the manufacturing of natural flavouring ingredients;
- Analytical methods to assess authenticity.

The intention of the document is to provide guidance to all flavouring manufacturers and food business operators on the processes that are regarded by EFFA as permissible in order to obtain natural flavouring ingredients. 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 they comply with the law.

A further objective of EFFA is to seek out any documentation that supports the self-policing of this Guidance Document, e.g. on analytical methods.

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@effa.eu or your respective National Association. EFFA welcomes the questions of its membership.

17 March 2010

EFFA Guidance Document for the Production of Natural Flavouring Substances and (Natural) Flavouring Preparations in the EU

General Introduction

This Guidance Document should be regarded as an additional platform that provides a consistent interpretation of what constitutes a natural process under Regulation (EC) No 1334/2008 on flavourings and certain food ingredients with flavouring properties for use in and on food, hereafter referred to as "The Regulation".

In this context it should be mentioned that the naturalness of the ingredient is not the sole regulatory requirement. The natural flavouring substance thus produced must comply with the appropriate regulatory specifications for that substance¹.

This Guidance Document is built up of six Chapters outlining the general principles, various processes and methods:

- Chapter I** General Principles
- Chapter II** Traditional food preparation processes
- Chapter III** Appropriate physical processes
- Chapter IV** Microbiological and enzymatic processes
- Chapter V** Processes used in the production of natural flavouring ingredients
- Chapter VI** Analytical methods to assess authenticity

With regard to the analytical methods as described in Chapter VI, it should be noted that their use in assessing the authenticity of natural flavouring substances has limitations. The user of the substances remains responsible for assessing compliance through documentation of the supplier / manufacturer and, if necessary, to initiate or conduct a full process audit and traceability at the manufacturer's premises.

¹ Such relevant (legal) instruments may be the EU-Union List, FCC, JECFA and national specification references (sometimes referred to as standard of identity, e.g. for ethyl acetate or ethyl butyrate) as applicable.

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, 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.

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CHAPTER I

General principles

1. Introduction

On December 31, 2008 Regulation (EC) No 1334/2008 on flavourings and certain food ingredients with flavouring properties for use in and on food, hereafter referred to as "The Regulation", was published.

EFFA has published extensive guidance on the general interpretation of the Regulation (EFFA guidance document on the EC Regulation on Flavourings: see EFFA Website: <http://www.ffa.eu/en>).

The Regulation amends the former definition of "natural" for flavours as stipulated in the former Directive 88/388/EEC. The current document provides a consistent interpretation of what constitutes a natural process under the Regulation. This interpretation:

- serves as a European Flavour Industry proactive proposition on the interpretation of Article 3.2(c, d, k) and Annex II of Regulation (EC) 1334/2008, while taking into account the scope of Recital (25),
- serves as a platform for the European (EFFA) Flavour Industry self-policing (for the distribution or sale or use of natural flavouring substances and flavouring preparations),
- constitutes the Guidance Document that should be taken as a basis for an EFFA Code of Practice on this subject,
- serves as a platform for explaining the same topic with other stakeholders within the EU and with IOFI.

In addition the document will provide guidance on the practical implications of self-policing instruments, e.g. the use of analytical techniques.

2. Regulatory framework

The Regulation defines natural in the Articles 3.2(c), (d) and (k). Recitals (16) & (25) reiterate the main guiding principles.

The applicable text is provided below for reference.

Recital (25)

Flavouring substances or flavouring preparations should only be labelled as 'natural' if they comply with certain criteria which ensure that consumers are not misled.

Article 3.2(c)

'natural flavouring substance' shall mean a flavouring substance obtained by appropriate physical, enzymatic or microbiological processes from material of vegetable, animal or microbiological origin either in the raw state or after processing for human consumption by one or more of the traditional food preparation processes listed in Annex II. Natural flavouring substances correspond to substances that are naturally present and have been identified in nature;

Article 3.2(d)

'flavouring preparation' shall mean a product, other than a flavouring substance, obtained from:

- food by appropriate physical, enzymatic or microbiological processes either in the raw state of the material or after processing for human consumption by one or more of the traditional food preparation processes listed in Annex II;
- and/or
- material of vegetable, animal or microbiological origin, other than food, by appropriate physical, enzymatic or microbiological processes, the material being taken as such or prepared by one or more of the traditional food preparation processes listed in Annex II;

Article 3.2(k)

'appropriate physical process' shall mean a physical process which does not intentionally modify the chemical nature of the components of the flavouring, without prejudice to the listing of traditional food preparation processes in Annex II, and does not involve, *inter alia*, the use of singlet oxygen, ozone, inorganic catalysts, metal catalysts, organometallic reagents and/or UV radiation.

Recital (16)

Regulation (EC) No 178/2002 defines food as any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be, ingested by humans. Materials of vegetable, animal or microbiological origin, for which it can be sufficiently demonstrated that they have hitherto been used for the production of flavourings, are considered to be food materials for this purpose, even though some of these source materials, such as rose wood and strawberry leaves, may not have been used for food as such. They do not need to be evaluated.

3. Requirements for the production of natural flavourings

The regulatory context of natural flavourings production is based on three cumulative requirements:

- The origin of the source material
- In the specific case of natural flavouring substances: the identification in nature of the manufactured flavouring substance
- The natural processes, their sequence and conditions thereof applied during manufacture

All three aspects are further detailed in the paragraphs below.

4. Source materials for the production of natural flavourings

The Regulation requires that sources of natural flavourings are material of vegetable, animal or microbiological origin in the raw state or after processing for human consumption by one or more of the traditional food preparation processes listed in Annex II.

Minerals are not listed as an accepted source.

EFFA considers that these sources may be foods as well as non-foods. Source materials for the production of natural flavouring ingredients may also include less routinely consumed parts of plant material as well as co- and/or by-products of food production such as fibre, hulls, stems, shells etc. (See in this respect Recital (16) of the Regulation.)

5. Identified in nature

In this section the term "identified in nature" is clarified and guidance is provided on the application of this definition to molecules that may exist as geometric and optical isomers.

5.1. Definition

The Regulation does not contain a definition of the term "identified in nature". The term identified in nature has been clarified in the EFFA guidance document on the Regulation as follows:

"Identified in nature" means:

- *identified in materials of plant, animal, microbiological, or mineral origin,² 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).*

EFFA considers that a process used to produce a natural flavouring substance or flavouring preparation may not in itself be used to qualify the resulting product as natural if the end product cannot be found in nature or in products traditionally used as foods by human beings.

² "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 (which should not be regarded as a source material for the preparation/production of natural flavouring ingredients).

5.2. Geometric and optical isomers

Flavouring substances may exist as distinct geometric isomers³ (Z/E, more commonly referred to as *cis/trans*). Mixtures of geometric isomers do not have to be produced in the same ratio as they are found in a specific food or in a natural source. If all geometric isomers have been identified in nature, the production of a mixture of geometric isomers in any ratio should be allowed.

Flavouring substances may have one or more chiral centres and hence can exist as different optical isomers (enantiomers and diastereoisomers resp.). Mixtures of optical isomers shall be allowed in any ratio provided that all the isomers are identified in nature.

If one of the geometric or optical isomers has not (yet) been identified in nature, it must be interpreted as an artefact of the natural process. Any flavouring substance thus produced would not qualify as natural unless the artefacts present are in small amounts that neither characterise nor contribute to the flavour of the natural ingredient.

5.3. Salts of natural flavouring substances

Salts of natural flavouring substances with cations such as NH_4^+ , Na^+ , K^+ and Ca^{++} or anions such as Cl^- , SO_4^{--} and CO_3^{--} are acceptable as natural flavouring substances. See Note 1 to the Union List (Regulation (EU) No 872/2012): "*Ammonium, sodium, potassium and calcium salts as well as chlorides, carbonates and sulphates are covered by the generic substances, providing that they have flavouring properties.*"

6. Natural processes

The Regulation clearly defines the sources which may be used in the production of natural flavouring ingredients. These are sources of vegetable, animal or microbiological origin and may or may not be processed according to the traditional food preparation processes which are listed in the Annex II. This difference is essential since it recognises that a number of vegetable, animal or microbiological sources already intrinsically contain flavour while other source materials only generate flavour during the food preparation process. The interpretation of traditional processes allowed under Annex II is covered in Chapter II.

The source material (whether processed or not) is subjected to physical, enzymatic or microbiological processes to obtain the flavouring substance or flavouring preparation.

Article 3.2(k) introduces a definition of appropriate physical processes as being processes which do **not intentionally** modify the chemical nature of the components of the flavouring. However, the phrasing "*without prejudice to the listing of traditional food preparation processes in Annex II*" in Article 3.2(k) acknowledges that processes that are listed in Annex II may be used irrespective of whether they induce such modification. In Chapter III detailed guidance is provided on the interpretation and practical implications of Article 3.2(k).

Enzymatic and microbiological processes do have the actual intention of chemically modifying the nature of the components and as such the legislator approves their use for this purpose. The regulatory context and practical implications for enzymatic and microbiological processes are covered under Chapter IV.

From the text of the Regulation it is clear that the traditional food preparation processes take place before the physical, enzymatic and microbiological processes. The physical, enzymatic and microbiological processes may be used sequentially and repetitively in any order as is also the case for the food preparation processes in Annex II. The Regulation does not provide any limitations to this extent. It must be emphasised that natural processes do not have to mimic the route of formation by which the flavouring substances or preparations are formed in the vegetable, animal or microbiological source and / or during traditional food processing.

A natural flavouring substance or preparation may be produced by consecutive steps involving a series of intermediates. Each step must be recognised as a natural process. However, the intermediates themselves do not have to be recognised as flavouring ingredients (substances) nor as food intended for human consumption as such.

Several processes may be used for the production of natural flavouring ingredients. To further facilitate a transparent view of the consecutive steps used in natural flavouring production and how they are covered in the Regulation, Chapter V provides an open-ended list of such processes and includes concise descriptions and conditions of use.

³ Positional isomers are different substances (with different CAS-numbers, identifiers and specifications) and are not the subject of this paragraph.

It should be noted that several processes may find useful application in different phases of the production of natural flavouring ingredients. To further facilitate a transparent view of the processes used in natural flavouring production and how they are covered in the Regulation, Chapter V provides an open-ended list of such processes and includes concise descriptions and conditions of use.

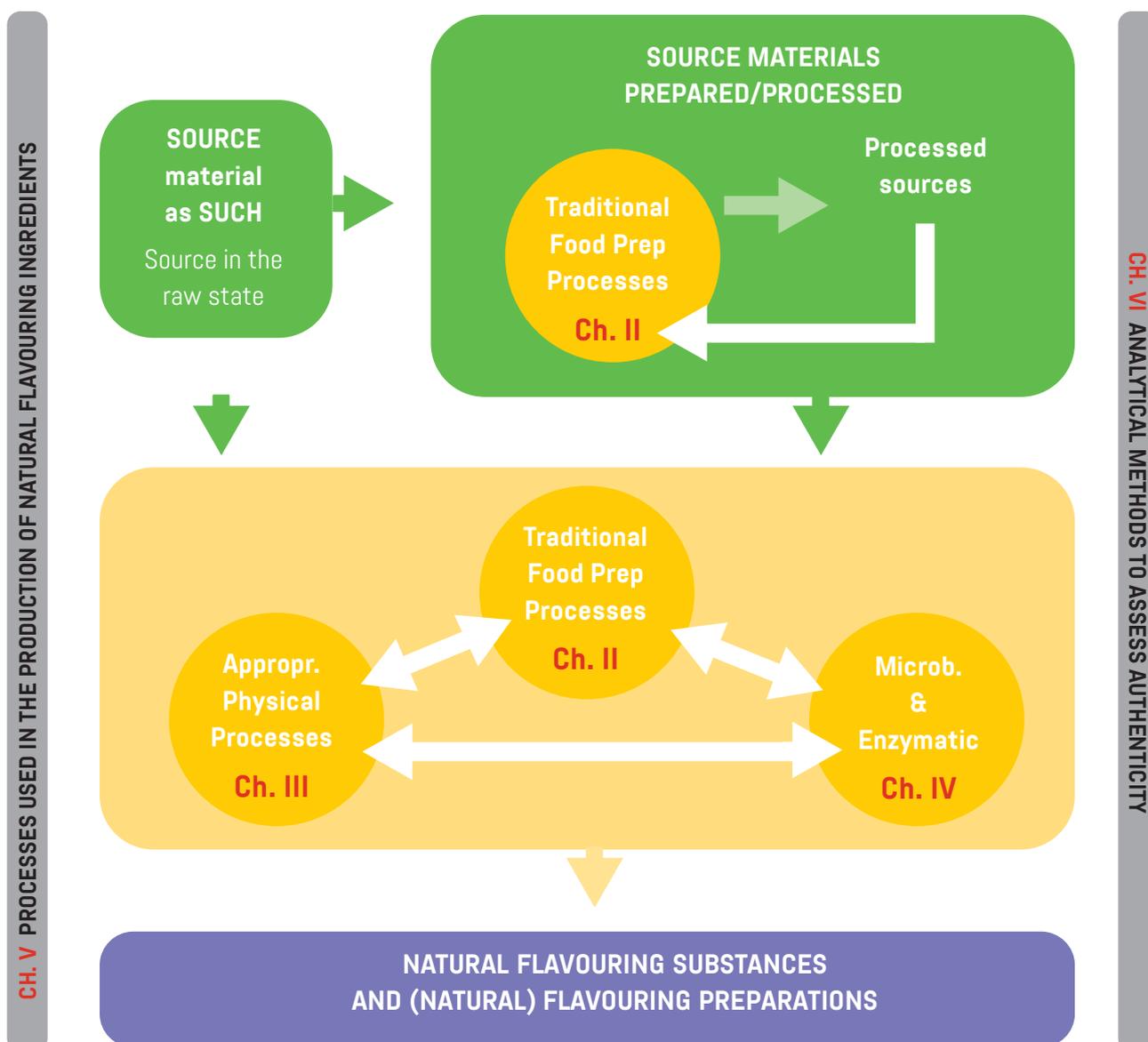
7. Self-policing

Every operator placing a natural product in the market is responsible for ensuring compliance with the Regulation. However, not every operator will be freely offered access by its supplier to the detailed process information required to qualify the natural claim. Chapter VI provides guidance on the potential use of analytical techniques to assess natural claims.

8. Schematic representation

For easy reference a pictorial representation of the interpretative guidance on the production of natural flavouring substances and flavouring preparations is provided below. The scheme includes (in red) the references to the respective Chapters in this Guidance Document.

FRAMEWORK SCHEME ON NATURAL PROCESSES



CHAPTER II

Traditional Food Preparation processes

1. Introduction

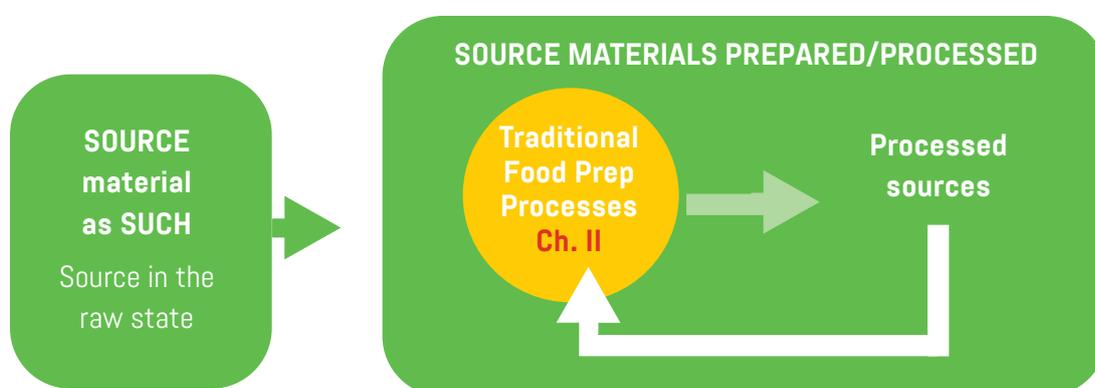
The Regulation defines the source materials from which natural flavouring substances or flavouring preparations may be obtained as follows:

Article 3.2 (c) & (d) "...food and / or material of vegetable or animal or microbiological origin either in the raw state or after processing for human consumption by one or more of the traditional food preparation processes listed in Annex II."

In this chapter the context of this definition is discussed, the legal text is interpreted and guidance notes are provided for appropriate industrial practice.

2. Regulatory context

The Regulation defines in Articles 3.2(c), (d)(i) and (d)(ii) the source materials which may be used in the production of natural flavouring ingredients, i.e. material of vegetable, animal or microbiological origin. These sources themselves may be food or non-food, either in the raw state or may be processed according to traditional food preparation processes which are listed in Annex II.



The regulatory context of the Article is important. The legislator herewith acknowledges that two distinct sources of natural flavouring ingredients exist:

- **Source Raw (Intrinsic)**

Natural flavouring ingredients may be intrinsic to the raw source from which they have been isolated. This is predominantly the case for products that originate from fruits, spices, herbs, meat, fungi, and yeast.

- **Source Processed (*in situ*)**

Natural flavouring ingredients may be formed from sources of vegetable, animal or microbiological origin as a result of food processing which may include microbiological and enzymatic processes. The natural flavouring ingredients are subsequently isolated from the processed source material.

The difference between raw and processed sources is essential since it recognises that a number of vegetable, animal or microbiological sources already intrinsically contain the flavour whilst other source materials only generate the flavour during the food preparation process. This view is consistent with the well-established definition for natural occurrence.

Summary:

Flavouring substances occur naturally either as an intrinsic component of the source material in the raw state and/or as formed during food processing.

3. Flavour formation during food processing⁴

Foods contain proteins, fats, carbohydrates, micro-nutrients, and other constituents. The interactions between all these constituents during food processing are numerous and complex: new materials are formed whereas others disappear. Some of these transformations have been extensively studied and can be described as Amadori and Heynes rearrangements, Strecker degradation, retro-aldol reactions, all of which are transformation steps that are part of non-enzymatic browning reactions, referred to as Maillard reactions⁵ and (hetero)cyclisation reactions.

The type of ingredients that are formed during food processing depend, amongst others, on the texture/composition of the source materials, the processes applied, the process conditions (time, temperature) and the water activity. The resulting ingredients are not necessarily present in the unprocessed source material and include nitrogen, sulphur and oxygen containing compounds such as pyrazines, pyrroles, thiazoles, trithiolanes, furans, and oxazolines.

In the table below some typical examples of flavour formation during food processing are concisely reviewed.

Table 1. Some typical examples of flavour formation during food processing

Source material	Process	Compounds
Onion	Cutting, cooking	Tissue disruption during cutting initiates the enzyme mediated production of the intermediate sulfenic acid along with ammonia and pyruvate. Further non-enzymatic reactions yield the characteristic lachrymatory substance thiopropanal S-oxide. Cooking enhances the formation of further reaction products of sulfenic acid, producing substances such as mercaptans, disulfides, trisulfides and thiophenes.
Cabbage (Brassica plants)	Cutting, cooking	Tissue disruption initiates the enzyme mediated production of the characterising isothiocyanates. Cooking destroys the isothiocyanates and promotes the formation of nitriles and sulphur-containing degradation and re-arrangement products.
Cocoa	Roasting	During roasting the characterising substance 5-methyl-2-phenyl-2-hexenal is formed by an aldol condensation from phenylacetaldehyde (from phenylalanine) and 3-methylbutanal (from leucine). ⁶ Other substances formed are pyrazines and heterocycles.
Coffee	Roasting	Extensive literature is available on the transformations (Strecker degradation and Maillard reactions) responsible for the formation of volatiles during coffee roasting. ⁷
Dairy	Fermentation	Lactic acid bacteria produce lactic acid, acetaldehyde and ethanol in milk cultures. Blue cheese produced by fermentation with <i>Penicillium roquefortii</i> is characterised by the formation of methyl ketones from fatty acids.
Meat, Fat	Frying	(E,E)-2,4-decadienal is produced from the oxidation/degradation of unsaturated fatty acids.
Caramel	Heating	4-hydroxy-2,5-dimethyl-3[2H]-furanone is produced by the thermal degradation-dehydration of sugars. ⁸
Cereal	Baking	Pyrazines and pyrrolines are produced from the thermal degradation of amino acids in the presence of sugars, following fermentation of the dough.

⁴ Food Chemistry third edition, edited by Owen R. Fennema. Marcel Dekker Inc. 270 Madison Avenue, New York, New York 10016 ISBN: 0-8247-9691-8. Chapter 11 by Robert C. Lindsay (p. 723–765). 1996

⁵ On Food and Cooking, the Science and Lore of the Kitchen. Harold McGee. Editor: Scribner, 1230 Avenue of the Americas, New York, NY 10200. ISBN 0-684-80001-2 (p. 778).

⁶ Phenylacetaldehyde and 3-Methylbutanal are themselves produced via the Strecker degradation of the respective L-amino acids phenylalanine and leucine.

⁷ Coffee Flavor Chemistry. Flament, Ivon. John Wiley & Sons, Ltd., West Sussex UK, 2002, pp 37-ff

⁸ The production of the flavouring substance 4-hydroxy-2,5-dimethyl-3[2H]-furanone by appropriate isolation from an intermediate complex mixture obtained by dehydration of rhamnose in the presence of the natural amino acids L-lysine and/or L-proline is consistent with the use of natural processes on natural raw materials. The mere fact that the intermediate complex mixture, obtained by heating a reducing sugar and a source of nitrogen (amino), when used as such without purification should be classified as a "process flavour" does not conflict with this position/statement.

Summary:

Natural flavouring substances are formed during food processing which are not known to occur in the raw source.

These flavouring substances are formed as a result of a cascade of transformations which often include both enzymatic and non-enzymatic pathways.

In particular, the thermal processing of food forms sulphur and nitrogen containing heterocyclic substances by non-enzymatic pathways.

4. Regulatory interpretation

Article 3.2(c) & (d) *"...material of vegetable or animal or microbiological origin either in the raw state or after processing for human consumption by one or more of the **traditional food preparation processes** listed in Annex II."*

It should be noted that the text refers to processes used in **traditional food preparation processes**, and not solely in domestic cooking practices. The list in Annex II is interpreted as covering food and food ingredient processes "traditionally" used in domestic cooking and industrial processing in the flavour and food related industries. In this context the word "traditional" is interpreted as being used to emphasise that a process listed in the Regulation should have a history of use (either domestic or industrial) and as such would be expected to be known to, and accepted by, the general public (familiarity).

In line with Article 22 and Recital (32) of the Regulation this list can be updated in the future. It has already been acknowledged that the list is incomplete, for example enzymatic processes are missing (cheese preparation). Another example is extrusion which is a process used in the production of, amongst others, breakfast cereals.

4.1. Subsequent processing

The allowable processes are not restricted to the type of source material and may be applied sequentially and repetitively in any order. In other words processes in the list in Annex II can be used for further processing of intermediate products/fractions (food and/or materials other than food) that were obtained during previous processing steps.

In the preparation of natural flavouring ingredients the flavour industry does not normally use the source as a whole but rather processes the specific fractions generating flavouring ingredients. In this respect, the flavour industry specifically isolates the flavouring substances only.

Summary:

- The traditional food preparation processes may be applied sequentially and repetitively in any order.
- These processes are applied to material of vegetable, animal and/or microbiological origin (being either raw or processed; being either food or non-food).
- It is acceptable to apply these processes so as to specifically optimise the yield of the flavouring substances from the food precursor.
- It is understood and accepted that the use of traditional food preparation processes may intentionally modify the chemical nature of the components of the food or food ingredient to which the process is applied.

5. Industrial implications

The use of processes by the flavour industry to obtain natural flavouring substances and flavouring preparations must conform to the regulatory interpretation presented above. In this section a number of guidance notes are formulated to further support a consistent interpretation of the requirements.

Ingredients

The materials to which the traditional food preparation processes may be applied are from animal or vegetable or microbiological origin, either in the raw state or from earlier processing.

These materials may be food or may be material other than food.

Process

The processes are those listed in Annex II or those deemed appropriate by EFFA (see also Chapter V).

The traditional food preparation processes may be applied sequentially and repetitively in any order.

The traditional food preparation processes are purposely applied to intentionally modify the chemical nature of the source material. The modifications are those which are demonstrated to occur (or likely to occur) during traditional food preparation processes or "as in the kitchen".

Catalysts

Article 3.2(k) on "appropriate physical processes" excludes, *inter alia*, the use of singlet oxygen, ozone, inorganic catalysts, metal catalysts, organometallic reagents and/or UV radiation.

Although not strictly formulated in the Regulation, EFFA considers that the same limitation applies to the traditional food preparation processes referred to in Article 3.2(c) & (d).⁹

Conditions

With the exception of frying and pressure cooking Annex II does not limit the conditions under which the processes are applied. However, EFFA considers the use of elevated time, temperature and pressure as unacceptable if applied to initiate a process which cannot be demonstrated to occur under the commonly accepted conditions of traditional food preparation processes.

Industrial processes are commonly applied in closed vessels for environmental considerations and for the safety of workers. These requirements dictate that industrial processes cannot necessarily be compared, one to one, with traditional food preparation processes. The industrialised (closed vessel) process may require the modification of physical parameters to yield an acceptable product. EFFA considers these modifications acceptable provided it is demonstrated that they do not alter the intrinsic characteristics of that process.

EFFA considers that temperature should be limited to 400°C (see also Chapter V). Pressure should preferably be maintained below 400 bars (conditions which may be reached in a typical supercritical extraction of herbs and spices).

Auxiliary agents

The use of auxiliary agents such as natural organic acids and bases is allowed to accelerate the formation of the desired product. In other words the auxiliary agent improves the yield of a conversion but is not essential for the transformations to occur and does not change the overall mechanism of formation.

Materials such as acids and bases used in transformations in which they are essential to initiate the conversion are not auxiliary agents but reactants. In this respect these materials should be regarded as source materials and shall be natural.¹⁰

⁹ For example the use of *p*-toluenesulfonic acid as an "organic soluble" acid catalyst is not permitted.

¹⁰ The use of natural occurring acid and base is for example allowed in ester hydrolysis, esterification, cyclisation (lactones formation) provided its use solely changes the reaction kinetics of an already existing equilibrium.

Annex II. List of traditional food preparation processes

Chopping	Coating
Heating, cooking, baking, frying (up to 240 °C at atmospheric pressure) and pressure cooking (up to 120 °C)	Cooling
Cutting	Distillation/rectification
Drying	Emulsification
Evaporation	Extraction, incl. solvent extraction in accordance with Directive 2009/32/EC
Fermentation	Filtration
Grinding	
Infusion	Maceration
Microbiological processes*	Mixing
Peeling	Percolation
Pressing	Refrigeration/Freezing
Roasting/Grilling	Squeezing
Steeping	

* The Flavour Industry considers these to include "enzymatic processes"

CHAPTER III

Appropriate Physical Processes

1. Introduction

The Regulation defines appropriate physical processes from which natural flavouring substances or flavouring preparations may be obtained as follows:

Article 3.2(k): '*appropriate physical process*' shall mean a physical process which does not intentionally modify the chemical nature of the components of the flavouring, without prejudice to the listing of traditional food preparation processes in Annex II, and does not involve, inter alia, the use of singlet oxygen, ozone, inorganic catalysts, metal catalysts, organometallic reagents and/or UV radiation.

In this chapter the context of this definition is discussed and an interpretation of the legal text is provided.

2. Regulatory context

Article 3.2(k) stipulates three distinctly different requirements which will be separately reviewed.

- ...*physical process which does not intentionally modify the chemical nature of the components of the flavouring...*
- ...*without prejudice to the listing of traditional food preparation processes in Annex II...*
- ...*and does not involve, inter alia, the use of singlet oxygen, ozone, inorganic catalysts, metal catalysts, organometallic reagents and/or UV radiation...*

2.1. A “physical process which does not intentionally modify the chemical nature of the components of the flavouring”

The Regulation refers to physical processes. A physical process may lead to a change in physical and/or chemical structure.

- Physical change means altering properties such as physical state (e.g., water versus ice) colour (e.g. intensification via concentration) and appearance.
- A change in chemical structure would be, for instance, a decomposition of constituents and/or formation of novel constituents.

Not in all cases is the difference clear. Some occasional cases may be argued as either a change in physical or in chemical structure. The solution of a salt in water is generally positioned as a physical process resulting in a physical change but it does involve the dissociation of the salt in the solution.

In the interpretation of the phrasing of “... *does not intentionally modify the chemical nature of the components of the flavouring*”, the term “*intentionally*” is the most important. Herewith the legislator has recognised and accepted to a certain extent that physical processes will induce a change in chemical structure (e.g., as a result of the chopping of fruits (e.g. apple) / vegetables (e.g. onion) new molecules may be formed via enzymatic browning).

The term “*intentionally*” in this context is interpreted as meaning processes where the primary intent is to chemically modify and to yield specific components not initially present (or not present in the desired quantity) in the source material, the abundance of which is critical for the organoleptic performance of the desired product. In all other cases the formation is interpreted as unintentional (unavoidable formation of by-product/artefact).

2.2. Physical processes within the context of “without prejudice to the listing of traditional food preparation processes in Annex II”

Article 3.2(k) determines an appropriate physical process as one which does not **intentionally modify** the chemical nature of the components of the flavouring. But the article 3.2(k) contains an important additional element stipulating “without prejudice to the listing of traditional food preparation processes in Annex II”.

The legislator herewith acknowledges that traditional food preparation processes often involve appropriate physical processes which may intentionally change the chemical nature of the components of the flavouring (i.e. cooking meat, baking bread, roasting coffee). Consequently only physical processes not listed in Annex II may not be used to intentionally modify the chemical nature of the components of the flavouring.

2.3. Physical processes within the context of “and does not ...UV radiation”

Article 3.2(k) specifically mentions that physical processes covered under this article may not “*inter alia*” use singlet oxygen, ozone, inorganic catalysts, metal catalysts, organometallic reagents and/or UV radiation in order to intentionally modify the chemical nature of the desired components.

The term “*inter alia*” is used to emphasise that the list of compounds included in the definition is not exhaustive but merely provides examples of chemical reagents typically used to intentionally or irreversibly modify the chemical nature of the components of the source material with which they are reacted. In the table below, the reagent groups are listed and typical representatives of each group are provided.

Table 2. Typical examples of reactions and reagent groups disallowed under Article 3.2(k)

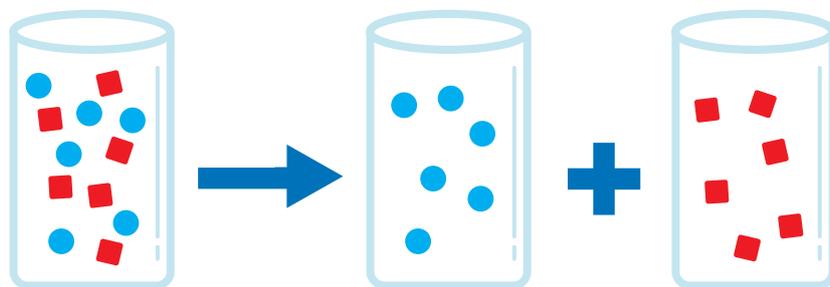
Reagent Group	Definition	Typical Representatives
Singlet oxygen, ozone	O ₂ in an excited phase.	Singlet O ₂ , O ₃
Inorganic catalysts or reagents	All chemical compounds that act as catalyst except those containing C-H bonds, metal catalysts and organometallic reagents.	HCl, H ₂ SO ₄ , NaOH, KOH, MgSO ₄ , LiAlH ₄ , KMnO ₄ , DiBAIH
Metal catalysts	Elemental metals.	Typical examples are Fe, Cu, Ni and Pd
Organometallic reagents	Chemical compounds containing bonds between carbon and metal that act as reagents.	Grignard reagents, organolithium reagents
UV radiation	Electromagnetic radiation with a wavelength in the range of 10 – 400 nm.	UV Light, Rose Bengal
Inter alia	Other non-natural catalysts, sources of radicals and reagents considered unacceptable by EFTA.	Hydroperoxides (such as tert.-butylhydroperoxide), pTSA, TEMPO, sodium ethoxide, sodium methoxide

3. Practical implications

Physical processing induces changes in the composition of the product in comparison with that of the starting material. As indicated in the previous section this has been acknowledged and accepted by the legislator. In this section these changes are characterised and discussed to the extent relevant for the interpretation of Article 3.2(k).

3.1. Segregation processes

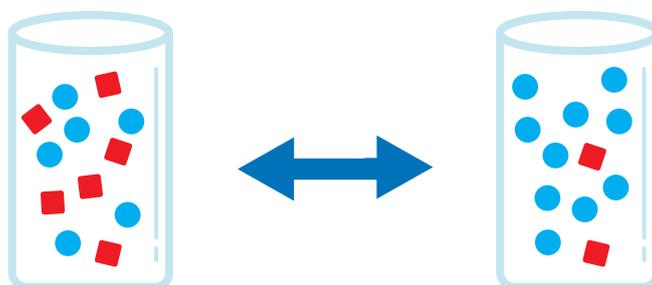
Physical processes used for isolation/purification may segregate or redistribute the starting material into two or more fractions, an example being simple phase separation in ambient conditions (e.g. oil/water phase separation in production of olive oils). Transformation of the chemical composition does not occur. A physical process fitting this description complies with Article 3.2(k).



Physical process segregates/redistributes components

3.2. Redistribution through shifting the equilibrium

A physical process applied for isolation/purification may influence the composition by changing the existing equilibrium between the constituents in the mixture, meaning the equilibrium will move to the most favoured composition from a thermodynamic perspective. This phenomenon will not introduce novel constituents in the composition, only the ratio of existing constituents will change.



Physical process shifts equilibrium

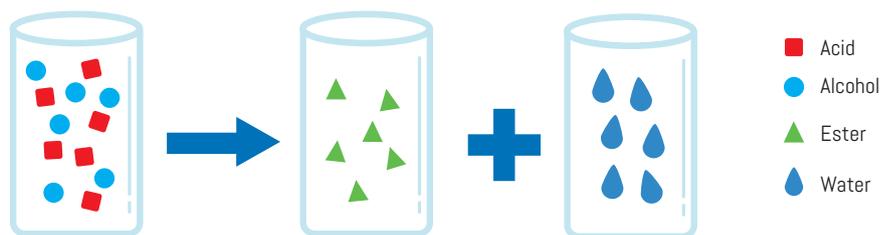
The extent to which this type of compositional change applies depends heavily on the constituents in the starting material, their stability, the type of physical processes applied and the conditions thereof. A physical process fitting this description complies with Article 3.2(k).

3.3. Novel formation

If the physical process introduces novel constituents the question of *intention* becomes relevant. It is acknowledged and agreed that physical processes applied with the intention of isolation/purification, and by which certain novel components may be unintentionally formed as artefacts (unavoidable by-products), are acceptable under Article 3.2(k).

For example during (steam) distillation to produce essential oils, novel terpenes, acids and alcohols may be formed by hydrolysis. The most well-known example of novel formation is lime oil. The organoleptic difference between cold pressed and distilled lime oil is due, inter alia, to the novel formation of alpha-terpineol from the conversion of citral in the presence of the citric acid naturally present in the lime juice.

However, a physical process applied for isolation/purification may also intentionally be used for the formation of constituents not identified in the starting materials (e.g. distillation process applied to intentionally form esters) (see Figure below). These novel constituents are formed as a result of a cascade of transformations initiated by the process applied and the conditions thereof.



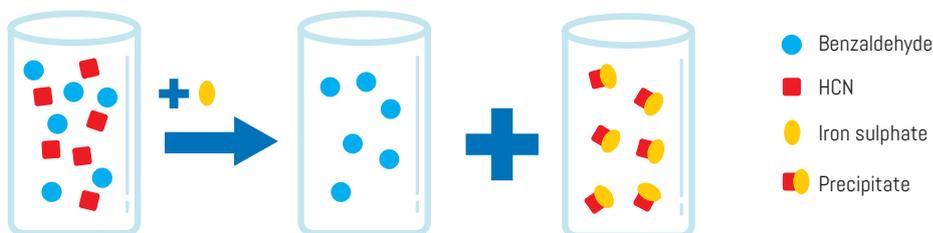
Physical process forms novel substances
(e.g. distillation process applied to intentionally form esters)

In cases where a process is designed such that it deliberately (intentionally) promotes the formation of novel substances rather than isolation / purification of the intrinsic substances, then the process applied must be a traditional food preparation process listed in Annex II.

3.4. Elimination processes

Elimination processes are very important in the flavouring industry. They may be applied to remove both undesired flavouring material as well as to remove undesirable non-flavouring components.

It should be mentioned that changes in chemical structure may be applied to remove non-flavouring components from the source material, for as long as the target material remains unchanged. There are important reasons to remove undesirable non-flavouring matter. One purpose is elimination of undesired ingredients, e.g. in the production of benzaldehyde from amygdalin ex prunus seeds (almond, *Prunus dulcis*; apricot, *Prunus armeniaca*) where the released Hydrocyanic acid (HCN) is precipitated with iron sulphate.



Material to be eliminated undergoes structural change, desired component remains unchanged

In this case, the eliminated substance is produced by/via a chemical reaction and cannot be deemed natural as it has undergone intentional chemical change (see also Chapter V under absorption/adsorption).

Summary:

- Physical processes applied in order to separate constituents into multiple fractions do comply with Article 3.2(k).
- Physical processes applied in order to move/shift the equilibrium of constituents do comply with Article 3.2(k).
- Physical processes applied with the intention of isolation/purification but by which certain novel components may be formed as artefacts (unavoidable by-products eliminated as much as possible) do comply with Article 3.2(k).
- Processes applied in order to eliminate undesirable components from the flavouring by changing the chemical nature of the components to be removed do comply with Article 3.2(k).
- Physical processes that are not listed in Annex II and are applied in order to intentionally modify the chemical nature of the components of the flavouring DO NOT comply with Article 3.2(k).

CHAPTER IV

Microbiological and Enzymatic Processes

1. Biosystems and Enzymes

Natural flavouring substances and flavouring preparations can be obtained by “enzymatic or microbiological processes”, amongst others (Article 3.2(c) and Article 3.2(d) of the Flavouring Regulation).

Biological entities comprising micro-organisms such as bacteria, yeasts and fungi, or higher organisms such as algae, plants or animals, used as such or in cell or tissue cultures, and enzymes derived thereof are permitted for the production of natural flavouring ingredients. The biological entities other than isolated enzymes will be referred to in the document as biosystems.

Biosystems are grown and/or maintained during a fermentation process. Since the terms ‘enzyme’ and ‘ferment’ are synonyms the term fermentation also refers to a process involving enzymes from microbial and non-microbial origin.

2. Biosystems

The biosystems used should be either those that are traditionally employed in food preparation or those that are regarded as safe (safe strain lineages) under the conditions used for the production of natural flavourings.

2.1. Definitions

Medium: In this context ‘medium’ refers to the mixture that is used to culture micro-organisms such as bacteria, yeasts and fungi or higher organisms such as algae, plants or animals cells and tissue cultures. Liquid media are generally but not exclusively aqueous mixtures of nutrients. Solid media are typically composed of solid organic material and/or aqueous mixtures of nutrients supplemented with a thickener such as agar. The medium has to be particularly suited/adapted to the biosystem.

Nutrients: ‘The substances from which microorganisms synthesize their cell material and obtain their energy’.¹¹ Flavouring materials obtained from biosystems may be derived in whole or in part from nutrients provided for this purpose.

Fermentation nutrients are generally classified as sources of carbon, nitrogen, sulfur, minerals and vitamins.¹² Nutrients are not restricted in origin (they do not need to be natural). However, the carbon source for the biosystem must be of natural origin or derived from CO₂ from air.

Substrates: Substrates are not usually defined for living entities (biosystems) such as bacteria. EFFA however considers that when the action of a biosystem has similarity with a single enzymatic conversion, the same restrictions should apply to the substrate/precursor as in an enzymatic reaction (see below: Enzymes).

Co-Factors, Nutrients, Hormones, etc: Materials used at any stage of the process, such as co-factors, minerals, nutrients, vitamins, hormones, pH adjusting agents, oxygen, nitrogen or carbon dioxide may only be used at levels required for the productive functioning of the biosystems. These materials are not restricted in origin (they do not need to be natural). Residual amounts of co-factors, minerals, nutrients, vitamins, hormones and pH adjusting agents shall be removed from flavouring preparations and natural flavouring substances to the greatest extent technically possible and shall not compromise the safety of consumers nor mislead them in violation of the general conditions of use as defined in Article 4 of the Regulation.

¹¹ *General Microbiology* by Hans G. Schlegel (1993), Press Syndicate of the Cambridge University, The Pitt Building, Trumpington Street, Cambridge CB2 1RP, 40 West 20th street, New York, NY 10011-4211, USA, page 193.

¹² *Fermentation and Biochemical Engineering Handbook, Principles, Process design and Equipment, second edition (PY)*. Edited by Henrt C Vogel and L Todaro. Chapter 3, “Nutritional Requirements in Fermentation Processes” (Willem H. Kampen), pages 122-160.

3. Enzymes

Until the application of the Community List of food enzymes as referred to in Article 17 of Regulation (EC) 1332/2008 on food enzymes, EFTA considers there should be no limitation to the origin of the food grade enzymes used.

However, enzymes utilised in the production of natural flavouring ingredients shall already comply with the remainder of Regulation (EC) 1332/2008.

3.1. Definitions

Substrates: 'The substance on which an enzyme acts, and which is activated by the enzyme, is termed the substrate of the enzyme'.¹³ All substrates in this context must be derived from vegetable, animal or microbiological sources either directly or after transformation by approved traditional food processes as described in Chapter II.¹⁴

Medium: The term medium is sometimes also used to characterize the 'reaction medium' of an enzyme (e.g. organic solvents listed in the Solvent Directive: 2009/32/EC (as amended) as extraction solvents for natural flavouring complexes; water, humidified gas etc.).

3.2. EFTA Guidance on Enzymatic processes

Although "Enzymatic processes" are not included as such in Annex II to Regulation (EC) 1334/2008 listing the "Traditional Food Preparation Processes", it is EFTA's understanding that the enzymatic processes are covered by the entry "Fermentation" listed in the Annex II.

4. General Requirements for Biosystems And Enzymes

Biosystems and enzymes cannot be used as 'alibis' for non-acceptable chemical processes.

Biotechnological processes should be thoroughly investigated in order to ensure that the described reaction is genuinely catalysed by the biosystem or enzyme. If the conditions of the reaction (pH, use of co-factors etc.) induces almost the same yield of product with or without the presence of the biosystem or enzyme then this clearly demonstrates a placebo effect. The reaction must be further scrutinised under a category other than those of the present Chapter.

Temperature, Pressure, etc: Temperatures and pressures which are applied are self-limiting since they should be compatible with the stability and efficiency of the biosystems or enzymes. Techniques such as sonication, mechanical disruption and enzymatic lysis may also be used for breaking up cell membranes.

Carriers: In a situation where there is a possibility that a carrier, for example, might react with the natural flavouring ingredient generated by the biotechnological process during isolation/purification then this reaction must comply with guidelines of EFTA on physical processes (Chapters II&III of this document).

Carriers may remain in the final product provided they comply with the Regulation (EC) No 1333/2008 on food additives.

Immobilisation Matrices: Immobilisation matrices are not limited provided that they are approved for food use.

Isolation/Purification: Any physical process used to recover, isolate or purify the flavouring substances or flavouring preparations formed by the biosystem or enzyme will not detract from their natural status provided they do not alter their chemical composition (see Chapter V).

¹³ *Enzymes* by M. Dixon and E.C. Webb, Academic Press Inc, Publishers, New York, 1958; page 5.

¹⁴ An example of a substrate that could not be used to produce a natural flavouring ingredient would be the use of a substance of mineral origin such as sodium sulfide where the sulfur atom is incorporated by enzymatic processes into the chemical structure(s) of the resulting flavouring ingredient.

CHAPTER V

Processes Used in the Production of Natural Flavouring ingredients

This Chapter provides an overview of all processes used to obtain natural flavouring substances and/or (natural) flavouring preparations.

All substrates for these processes are required to be eligible for qualification as natural according to this EFFA Guidance Document.

As the Flavour Industry in Europe we have always alerted our membership on other legislation, e.g., solvent extraction Directive, and therefore drafted our Guidance document to establish a clear preference for those solvents that are permitted by the Directive 2009/32/EC as amended.

1. List of all permissible processes

The processes listed below are further described in this Chapter. The limitations and permissibility of each process, in the opinion of EFFA, is also discussed.

This list is an open, positive list and is neither exclusive nor restrictive: it may be expanded after submission to, and discussion within, EFFA.

ABSORPTION	GRINDING
ADSORPTION	HEATING, COOKING (including Extrusion Cooking), BAKING, FRYING
AGGLOMERATION	INFUSION
CENTRIFUGATION	ION EXCHANGE
CHOPPING	LYOPHILIZATION
CHROMATOGRAPHY	MACERATION
COATING	MICROBIOLOGICAL PROCESSES
COOLING	MIXING
CRYSTALLIZATION	OSMOSIS
CUTTING	PEELING
DIGESTION	PERCOLATION
DISTILLATION/RECTIFICATION	PRECIPITATION
DRYING/VACUUM DRYING	PRESSING
ELECTROPHORESIS	REFRIGERATION/FREEZING
EMULSIFICATION	ROASTING/GRILLING
ENCAPSULATION	SALTING OUT
ENZYMATIC PROCESSES	SQUEEZING
EVAPORATION	STEEPING
EXTRACTION	SUBLIMATION
FERMENTATION	ULTRASONIC TREATMENT
FILTRATION	

2. Description of all processes – Definitions

ABSORPTION

ADSORPTION

This is restricted to processes in which the starting material is recovered intact and in which the adsorbent is not purposely used as a catalyst for an irreversible chemical conversion of a natural substrate into another substance.

This applies to mixtures as well as individual substances.

Example of an allowable use of adsorbent: to remove impurities (even after chemical transformation of this impurity on the adsorbent, provided this by-product does not qualify for the labelling of Natural Flavouring Substance) from a crude natural flavouring substance obtained by a natural process.

E.g.: Mixture (A & B) gives (A & C) where B is converted to C

A = natural substance untouched by the adsorption process (to be purified)

This process leaves A intact while B is converted into C and removed (C **cannot** be regarded as a natural substance).

Another example of an allowed use of an adsorbent is the use of activated charcoal to remove or standardize the colour of essential oils, provided the activated charcoal does not purposely alter the chemical composition of other constituents of the essential oil, e.g. by isomerisation.

Example of an unacceptable use: the conversion of citronellal to isopulegol purposely promoted by adsorption on silica gel because this is not in line with provisions of Article 3.2(k).

The use of ion exchange resins is a further example of adsorption on a support and is detailed later.

AGGLOMERATION

This process is usually used to modify the particle size of a product. The simplest way is to use a fluidized bed into which a powder is introduced, moistened and agglomerated. Other equipment can be used (rotogranulators, vortex granulators, compactors...).

If a binding agent is used it must comply with the appropriate legislation.

CENTRIFUGATION

The purpose of centrifugation is to separate two liquids or solid/liquid mixtures which are not miscible with each other (e.g. centrifugation of cold pressed essential oils of citrus away from the water phase created by squeezing and washing citrus peels).

Centrifugation can also be used to separate the solvent phase from the water phase in an extraction step, prior to removal of the solvent in vacuo.

Centrifugation can also be used to purify extracts from suspended particulate matter which would otherwise only settle after a long period of time.

CHOPPING

See under CUTTING.

CHROMATOGRAPHY

This is a separation process which is used for preparative purposes.

Low pressure column chromatography, HPLC and GLC, either preparative and/or chiral, can be used.

For the production of natural flavouring ingredients, all solvents that are acceptable according to the EFFA Guidance Document can be used for chromatography – the solvents do not have to be natural themselves.

Solvents for this use are preferably those solvents permitted by the Directive 2009/32/EC on extraction solvents and its subsequent modifications.

Indeed, EFFA recognizes that other eluents may be used as well. In the absence of regulations, the residue limits as listed in the IOFI IL 1352 and its attachments are considered as appropriate.

Chromatography should not be used to trigger isomerisation or act as an alibi for chemical transformation because this is not in line with provisions of Article 3.2(k).

Chromatography should only be used on substrates which are produced via an acceptable natural process. Example of unacceptable use: preparative chiral chromatography of racemic gamma-undecalactone prepared by isomerization of undecylenic acid with highly concentrated mineral acid (such as H₂SO₄).

COATING

No particular comments.

COOLING

This process lowers the temperature of a product or the solution of a product. A synonym is "refrigeration".

In Traditional Food Preparation Processes, cooling (principally of liquids or of the surface of solids) slows down oxidation caused by oxygen in air. It also reduces the modification of the food composition via its own enzymes and spoilage initiated by surface or air borne bacteria and other microorganisms.

Solidification of a liquid by lowering its temperature is called "freezing" (e.g. of water into ice). Other types of "freezing" include "deep freezing" of vegetable and animal substrates to facilitate their preservation for transportation purposes, or to prolong their shelf-life either for direct consumption or for further processing.

See "freeze drying" under DRYING.

In purification processes, cooling can be used to induce a variety of outcomes:

- crystallization of a substrate to be purified (see under "Crystallization");
- precipitation of undesirable material in a solvent solution (e.g. maceration, infusion) in order to clarify that solution ;
- precipitation of undesirable waxes (e.g. dewaxing of citrus essential oils).

CRYSTALLIZATION

This is a process for purifying solid substances from their impurities.

For the production of natural flavouring ingredients, all solvents that are acceptable according to the ECHA Guidance Document can be used for crystallisation – the solvents do not have to be natural themselves.

Solvents for this use are preferably those solvents permitted by the Directive 2009/32/EC on extraction solvents and its subsequent modifications.

Indeed, ECHA recognizes that other eluents may be used as well. In the absence of regulations, the residue limits as listed in the IOFI IL 1352 and its attachments are considered as appropriate.

CUTTING

There are many definitions of cutting :

- making "cuts" as from a **fractional distillation** process,
- standardization of, for example, an oleoresin with an approved diluent or edible solvent (e.g.: standardization of ICU or Scoville Units with vegetable oil, addition of a solubilizer to an oleoresin etc.),
- dicing, chopping or comminuting fresh vegetables.

Note: in certain cases of food preparation processes, chopping or cutting fresh foods may induce unavoidable chemical modifications. For instance, chopping fresh garlic will provoke rupture of certain cell membranes and contact between a precursor (alliin) with an in-built enzyme (alliinase) transforming the precursor into volatile substances which are not naturally occurring inside the fresh garlic pod.

DIGESTION

Digestion is understood as a form of enzymatic conversion. See Chapter IV.

DISTILLATION/RECTIFICATION

Distillation is a very wide-spread process.

For the production of natural flavouring ingredients, all solvents that are acceptable according to the EFTA Guidance Document can be used for distillation/rectification – the solvents do not have to be natural themselves.

AZEOTROPIC DISTILLATION

Azeotropic distillation is a generally accepted process. The continuous removal of water is an example.

Solvents for this use are preferably those solvents permitted by Directive 2009/32/EC on extraction solvents and its subsequent modifications.

There is no limitation as regards time or temperature.¹⁵

FRACTIONAL DISTILLATION

Fractional distillation can be performed under vacuum or under pressure (e.g.: the purification of ethanol).

It is acceptable provided :

- the packing of the column does not intentionally induce irreversible chemical transformations of the substrates being fractionated,
- the process is not purposely used to induce chemical transformations that generate artefacts, isomers and other substances not identified in nature.

MOLECULAR DISTILLATION

Is acceptable provided any non food-grade solvents used as fluidisers or diluents remain **exclusively** in the residue.

RECTIFICATION

"Rectification" is a distillation process by which some portion of a natural substrate is removed by distillation for the purpose of standardization and to ensure compatibility of the substrate with established quality standards or specifications (e.g. the removal of the non-volatile portion from an essential oil).

However, "rectification" may encompass other commonly accepted processes such as the "topping" or "tailing" of essential oils and the continuous feed process utilised in the rectification of ethanol.

STEAM DISTILLATION

Steam distillation occurs when, for instance, vegetables are boiled or pressure cooked: the generation of water vapour or steam inevitably leading to a loss of the most volatile flavouring substances from the food. Alternatively, steam can react with some of the flavouring substances contained in the substrate and transform them by hydrolysis. This can occur in the presence of a native enzyme such as during the distillation of bitter almond oil. Here the formation of the benzaldehyde rich essential oil is as a consequence of the hydrolysis of a precursor and the co-generation of hydrocyanic acid (which has to be carefully removed so as not to present a hazard to the operator). Similarly, the steam distillation of rose inevitably leads to the formation of racemic linalool (not present in the headspace of rose) generated by the allylic transposition (hydration and dehydration) of geraniol which is naturally occurring.

DRYING/VACUUM DRYING

Acceptable processes include **spray-drying**, **freeze drying**, **vacuum drying** and **microwave drying** of herbs, spices etc. All these processes are susceptible to the loss of some flavouring components.

ELECTROPHORESIS

EFTA could not suggest any industrial application of this process and questions its relevance to the Flavour Industry.¹⁶

EMULSIFICATION

This is considered a necessary technology in fermentative bioprocessing (e.g. the use of lipases in bioconversion) and for spray-drying. The emulsifiers are required to be approved for use in flavourings and/or food in the case of lipase bio-processing and for flavourings only when spray-drying.

¹⁵ EFTA considers that the nature of the solvents allowed is self limiting to acceptable temperatures.

¹⁶ One of the members of EFTA has seen a patent on the isolation of propionic acid by *electrodialysis*.

ENCAPSULATION

Only carriers and encapsulating agents which are approved for use in flavourings are allowable.

ENZYMATIC PROCESSES

The use of enzymes in the manufacturing processes for flavouring preparations and/or natural flavouring substances is authorized within the applicable legal requirements for the use of such enzymes in the EU.

See Chapter IV.

EVAPORATION

Transformation of a liquid into a vapour.

EXTRACTION

Solvents for the production of flavouring preparations are restricted to those permitted by Directive 2009/32/EC on extraction solvents and its subsequent modifications.

The additional use of ultrasound or microwaves in the extraction process is allowed.

The use of carriers as co-solvents (e.g.: propylene glycol, triacetin etc.) which are legally approved for the dilution of flavourings is also allowable. In this case, these carriers remain in the flavouring preparation. However, it is strictly forbidden to purposely introduce these carriers in order to form artefacts (e.g.: dioxolanes, acetals, or hemiacetals, etc.). Conversely, artefacts (especially acetals) are known to form unintentionally during solvent extraction of spices and herbs containing aliphatic aldehydes and during the distillation of spirits.

Extraction is widely used as a purification process to remove metabolites from fermentation broths for instance, or to extract flavouring substances which are highly water soluble. Solvents used for the production or purification of natural flavouring substances are preferably those permitted by Directive 2009/32/EC on extraction solvents and its subsequent modifications or are themselves foodstuffs (e.g. edible oils).

FERMENTATION

In traditional food preparation processes fermentation is undoubtedly used to transform precursors into other types of molecules and of course flavouring substances (e.g.: beer, cheese or wine making).

The use of micro-organisms in the manufacturing processes for flavouring preparations and/or natural flavouring substances is authorized within the applicable legal requirements for the use of such organisms in the EU.

See Chapter IV.

FILTRATION

Membrane Filtration (Ultrafiltration, Pervaporation and Reverse Osmosis) and other modes of filtration (cloth, filter press, etc.) are allowed in the same way they are used to produce ingredients for the Food Industry.

GRINDING

No particular comments. See CUTTING.

HEATING, COOKING (including EXTRUSION COOKING), BAKING, FRYING

EFFA recommends temperatures similar to those obtained in the other traditional food preparation processes:

- heating,¹⁷
- cooking (including extrusion cooking),
- baking,
- frying (up to 240°C at atmospheric pressure) and
- pressure cooking (up to 120°C).

Heating in the presence of air such as in frying or stir-frying leads to the production of many degradation and oxidation products from non-saturated lipids, for instance as a result of the decomposition of hydroperoxides.

¹⁷ 240°C limitation as for frying does not apply to heating – temperatures exceeding 240°C should remain exceptional, e.g.: the cleavage of fats with superheated steam is performed industrially at temperatures around 250°C.

Extrusion Cooking is an increasing ubiquitous traditional process to extrusion as a lower energy, more rapid way of cooking food.

Extrusion cooking can only be used within the conditions (pressure, temperature) which are appropriate for the processing of conventional foods (such as biscuits, cereals, expanded snacks, textured vegetable proteins etc.).

INFUSION

This is the solubilisation of extractibles from a plant or animal substrate into an appropriate edible solvent, typically water or ethanol, or mixtures thereof.

Removal of the spent material is achieved with pressing, filtration, centrifugation, etc.

The unintentional formation of acetals cannot be avoided, especially if the substrate and the solvent offer the appropriate pH conditions for this to occur.

A synonym is maceration, mostly used to qualify an infusion in ethyl alcohol or fats and oils.

ION EXCHANGE

Ion exchange should be limited to the sole purpose of pH adjustment during the isolation of acids and bases.

LYOPHILIZATION

See under DRYING (freeze drying).

MACERATION

See under INFUSION.

MICROBIOLOGICAL PROCESSES

The use of micro-organisms in the manufacturing processes for flavouring preparations and/or natural flavouring substances is authorized within the applicable legal requirements for the use of such organisms in the EU.

See Chapter IV.

MIXING

No particular comments.

OSMOSIS

EFFA only considers reverse osmosis as relevant to the Flavour Industry. See under FILTRATION.

PEELING

This is the physical removal of the skin, shell or outer envelope of a natural substrate to be further processed (e.g. peeling of fruit, shelling of pistachios, filberts etc.). The process "chemical peeling", with e.g., KOH is not considered by EFFA as a traditional food preparation process listed in Annex II and thus not allowed as a "natural process".

PERCOLATION

This is a particular form of extraction by which a solvent is forced through stacks of comminuted natural substrate contained within an appropriate extraction vessel, either by pressure (e.g. percolation of coffee in pressurized extractors¹⁸) or by circulation (e.g. percolation of chopped vanilla beans by a hydrated alcohol).

PRECIPITATION

Precipitation is used mainly to eliminate undesirable impurities during a purification step (e.g. the precipitation of undesirable minerals from the crystallization of glycosidic compounds).

PRESSING

Pressing of oil seeds to obtain 'first pressing oil' for instance.

¹⁸ Coffee percolation machines using super heated steam usually work at pressures around 16 bar.

ROASTING/GRILLING

There are different kinds of roasting processes, or processes which are analogous to roasting, which must be considered under this heading.

CONVENTIONAL ROASTING (such as the roasting of coffee, tea, cocoa, seeds, nuts, vegetables etc.)

Involves self-limiting temperatures and air flow that ensure that the resultant flavour is palatable and acceptable for human consumption.

GRILLING

This is a traditional cooking process in which dry heat is applied to the surface of a foodstuff.

This normally takes place at atmospheric pressure in the presence of air.

The temperature at which grilling occurs is recommended not to exceed 400°C.

The use of a pure oxygen atmosphere is forbidden. "Grilling" must occur as it does in the kitchen, either in an open or closed environment.

THERMAL DECOMPOSITION

Thermal decomposition of a suitable source material (See Chapter I) can also be used to generate natural flavouring substances. As above it is recommended not to exceed a temperature of 400°C. An example is the formation of *n*-heptanal from castor oil.¹⁹

SALTING OUT

Separation of a water soluble material may be effected by the saturation of a salt (e.g. NaCl) in the water phase in order to reduce the solubility of the material and effect its "oiling out". The product is separated by decanting, centrifugation, etc. (e.g. salting out of terpeneless and sesquiterpeneless citrus oils from "weak" ethanolic solutions).

STEEPING

No particular comments.

SQUEEZING

An example is the production of apple juice or lemon juice by squeezing of the respective fruit.

Synonym: PRESSING.

SUBLIMATION

This is a natural process used to purify natural flavouring substances or separate them from undesirable tar or polymeric materials (e.g. separation of maltol from fir balsam).

ULTRASONIC TREATMENT

See EXTRACTION

¹⁹ According to Kirk-Othmer's Encyclopedia of Chemical Technology, the pyrolysis of castor oil at 340-400°C splits the ricinoleate molecule at the hydroxyl group to form heptanal and undecylenic acid.

- Jean Garnero reports in Rivista EPPOS (October 1973) that the pyrolytic distillation of castor oil starts becoming effective at 280°C. Then temperature raises and stabilizes between 300 and 340°C.



Introductory and Descriptive Note

- This Annex consolidates within its first column the various lists of processes used in the production of Natural Flavouring Substances and (Natural) Flavouring Preparations.
- The second column lists those traditional food preparation processes as per Annex II of the Regulation (Chapter II of this Guidance Document).
- The third column lists those physical processes which are commonly used for the purification of Natural Flavouring Substances in the EU by the Flavour Industry.
- The fourth column lists those processes which are most commonly used in microbiological and enzymatic processes (Chapter IV of this Guidance Document).
- The fifth column lists other processes currently in use in the EU by the Flavour Industry which are not appropriately or exhaustively described in the Chapters II to IV of this Guidance Document.
- The sixth column lists those processes which are currently considered to be useable for the production of Natural Flavouring Ingredients in the latest version of the IOFI Code of Practice.

PROCESS (APPROPRIATE PHYSICAL AND/OR TRADITIONAL FOOD PREPARATION)	<i>Food preparation process (generation) [Annex II]</i>	<i>Purification process</i>	<i>Microbiological and enzymatic processes</i>	<i>Other process</i>	<i>Process as per IOFI CoP</i>
Absorption		•			•
Adsorption		•			•
Agglomeration		•			
Centrifugation		•			
Chopping	•				
Chromatography		•			
Coating	•				
Cooling	•	•			
Crystallization		•			•
Cutting	•				•
Digestion			•		
Distillation/rectification	•	•			•
Drying/Vacuum Drying	•	•	•		•
Electrophoresis		•			
Emulsification	•		•		•
Encapsulation				•	•
Enzymatic Processes	•		•		
Evaporation	•				
Extraction	•	•			•
Extrusion				•	•
Fermentation	•		•		
Filtration	•	•			•

Continued on next page

PROCESS (APPROPRIATE PHYSICAL AND/OR TRADITIONAL FOOD PREPARATION)	Food preparation process (generation) [Annex II]	Purification process	Microbiological and enzymatic processes	Other process	Process as per IOFI CoP
Grinding	●				●
Heating, Cooking (including Extrusion Cooking), Baking, Frying	●				●
Infusion	●				
Ion exchange		●			
Lyophilization		●		●	
Maceration	●				
Microbiological processes	●		●		
Mixing	●	●			●
Osmosis		●			●
Peeling	●				
Percolation	●				
Precipitation		●			●
Pressing	●	●			
Refrigeration/Freezing	●	●			
Roasting/Grilling	●				●
Salting out		●			
Squeezing	●				●
Steeping	●				
Sublimation		●			●
Ultrasonic treatment				●	●

Examples for production pathways of natural flavouring ingredients are given in Attachment IIc:



Attachment IIc:

- Example 1: Natural Flavouring: Fish Extract
- Example 2: Natural Flavouring: Cooked Onion Extract
- Example 3: Natural Flavouring: Methyl Butyric Acid
- Example 4: Natural Flavouring: Gamma Decalactone

CHAPTER VI

Analytic Methods to Assess Authenticity

1. Preamble

The analytical methods outlined in this document find useful application in the review of the authenticity of natural flavouring substances. For each type of analysis EFFA has identified which kind of transformation pathway may be characterized by the method. If, and where, applicable interpretative limitations to the method have been included.

The methods of analysis as laid down in this document are for the sole purpose of identifying compliance with the natural processes as laid down in Chapter I. These analytical techniques are not necessarily suitable for the identification of the natural source from which they are produced (source authentication).

The analytical techniques which are recommended herein to establish the naturalness of a given process should have been published in a peer-reviewed publication and preferably validated by a round-robin analysis. If a standard round-robin test has not been performed, a method where the repeatability and/or the reproducibility (or other statistical tests) has been evaluated should be preferred.

A method without the previous characteristics can be suggested, but cannot be considered as recommended until validated by a group of Flavour Industry analytical experts (such as the IOFI WGMA) or another official authority.

EFFA recognizes that analytical methods are not static and the opinions contained herein should be periodically reviewed pending the publication of new methods or refinements.

All necessary precautions should be exercised when isolating the substance to be analysed from a complex mixture or substrate since the process itself may affect how representative it is of the original substance (e.g. enantiomeric excess affected by pH; discrimination of certain isotopes by distillation/extraction processes).

When a single method fails to bring a clear answer about the authenticity of a natural process, the association of several methods may help to draw a more conclusive and robust diagnosis.

EFFA recognizes there are differences between the analytical methods which assess source authenticity and those which can be used to assess the naturalness of a process. The available analytical techniques are generally more likely to be useful in the discrimination of the source of the flavouring substances. However, to repeat, the methods of analysis laid down in this document focus solely on those used to identify compliance with the natural processes as elucidated in Chapter I.

EFFA emphasizes that the use of analytical methods in assessing the authenticity of natural flavouring substances has limitations. The user of the substances remains responsible for obtaining compliant documentation from the supplier / manufacturer and, if necessary, to initiate or conduct a full process audit and traceability at the manufacturer's premises.

2. Use of Discriminating Analytical Methodology

2.1. Fingerprint Analysis

Field of application: Examination of impurities characteristic of a natural process or a non-natural process. The presence of trace impurities could indicate the synthetic nature of the process.

Examples: the use of a strong mineral oxidant for the conversion of 2-methylbutanol to 2-methylbutyric acid may lead to the presence of 2-hydroxy-2-methylbutyric acid.

A careful inspection by GLC is also recommended in the case of substances that can be produced by aldolization (e.g. cinnamaldehyde).

2.2. Chiral Analysis

Field of application: Chiral analysis has shown to be a reasonably effective analytical method when reviewing the source authenticity of juices and nectars.

Chiral analysis is even more effective when coupled with an isotopic method such as chiral GC/IRMS (isotopic ratio mass spectrometry).

Publications²⁰ on citrus oils report that the enantiomeric excess of terpenic alcohols (α -terpineol, terpinen-4-ol and linalool) can vary as a function of fruit maturity (bergamot, lemon) or production process (distillation in the presence of low pH juice induces high levels of racemization). Terpenes may also show considerable variations in a single species owing to the geographic area of cultivation or the hybrids cultivated.

The high enantiomeric purity of a given flavouring substance is no guarantee that the material has been produced by a natural process. Examples of processes producing almost pure enantiomeric substances and which are not eligible to qualify as natural are:

- the resolution by enzymes or micro-organisms of a racemate obtained by a non-natural process, possibly after derivatization of the enantiomers of the racemic mixture;
- the resolution of lactones or other racemates obtained by a non-natural process by physical means such as HPLC or GLC with a chiral column or any other chromatographic process;
- the production of optically active flavouring substances by chemical modification of an optically active natural substrate (e.g. the conversion of *d*-limonene from orange oil into *l*-carvone or the hydrogenation of menthone to menthol by a chemical reaction).

2.3. Site Specific Deuterium NMR

Field of application: This method can be useful in the discrimination of natural processes involving hydrogen at "characteristic" positions on the molecule.

The analysis may be applied to e.g. the oxidative degradation of eugenol to vanillin. Oxidation through a non-natural process would normally give a deuterium enriched carbonyl hydrogen whereas biosynthesis would give a lower deuterium value on the carbonyl site.

The method also finds useful application in the discrimination between a natural process involving enzymes (*vide supra*) and chemical hydrogenation e.g.:

- on the carbon bearing the alcohol functionality in the case of the reduction of a carboxylic group (acid, ketone or aldehyde);
- on the two adjacent carbons receiving the hydrogen atoms in the case of the reduction of a carbon-carbon double bond (e.g.: the enzymatic reduction of massoia lactone to D-decalactone).

²⁰ *Enantiomeric distribution of volatile components of citrus oils by MDGC* – G. Dugo, L. Mandella, A. Cotroneo, I. Bonaccorsi and G. Lamonica – *Perfumer & Flavorist*, Vol. 26, January/February 2001.

+ "Multidimensional capillary GC-GC for the analysis of real complex samples. Part II. Enantiomeric distribution of monoterpene hydrocarbons and monoterpene alcohols of cold-pressed and distilled lime oils" – L. Mondello & al – *J. Microcolumn Separations*, 10(2), 203-212 (1998).

2.4. IRMS (Isotope Ratio Mass Spectrometry) / SIRA (Stable Isotope Ratio Analysis) Coupled with High Resolution Gas Chromatography (HRGC), Chiral Multidimensional Gas Chromatography (MDGC) or Elemental Analyzer with Combustion or Pyrolysis Mode (EA-C or EA-P)

2.4.1. Carbon SIRA

Field of application: EFTA is unaware that this method can be used in the authentication of a natural process. Typically it is used in the assessment of the natural origin of the raw materials used. For instance it offers the possibility of differentiation between C_3 -, C_4 - and CAM plant material versus synthetic source material.

2.4.2. Deuterium SIRA

Field of application: All processes likely to exchange hydrogen atoms in the target molecule.

The literature²¹ shows that the global deuterium abundance of (*E*)-2-hexenal seems to be higher than that of (*E*)-2-hexenol when both are produced by the same plant through a cascade of enzymatic reactions. This suggests that a kinetic isotope effect occurs in the course of the enzymatic reduction.

Confirmation of the naturalness of a process can be based on the comparison of the deuterium abundance in the aldehyde and the corresponding alcohol provided:

- the water used for the steam distillation and isolation of these flavouring substances has no effect on the labile hydrogen of the hydroxyl group;
- the pH of the steam distillation is maintained neutral;
- chemical reduction of the aldehyde with hydrogen from common hydrides or catalytic hydrogenation shows significant discrimination from variations seen naturally.

2.4.3. Oxygen SIRA

Field of application: Verification that the extraneously introduced oxygen comes either from a natural source (air in the case of fermentation) or from a disallowed oxidation agent (mineral origin).

This method of analysis is applicable to oxidation of natural alcohols to carboxylic acids (e.g. natural butyric acid from natural *n*-butanol) since the extra oxygen either originates from air (fermentation) or from the oxidation chemical (when a strong mineral oxidant is used).

In the case of the enzymatic oxidation of a natural secondary alcohol to a natural ketone, the oxygen 18 to oxygen 16 ratio should remain unchanged. The same may apply to the conversion of a primary alcohol to an aldehyde but EFTA considers that the possibility of oxygen scrambling from the fermentation medium cannot be excluded and warrants further investigation.

2.5. ^{14}C Radiocarbon Determination

Field of application: EFTA is unaware that this method can be used in the authentication of a natural process. Typically it is used in the assessment of the natural origin of the raw materials used.

If a flavouring substance analysed by radiocarbon analysis is found devoid of any radioactivity, this is a **robust proof** that the material has been generated from fossil fuel substrates.

Flavouring substances can be considered to have a "modern" activity when they show typical radiocarbon determinations between 100-115% of the standard modern activity of 14.5 dpmg ($\pm 5\%$). Radiocarbon activity below 13.8 dpmg may be indicative of mixtures of natural flavouring substances with their non-natural counterparts.

²¹ Flavor authenticity studies by 2H/1H ratio determination using on-line gas chromatography pyrolysis isotope ratio mass spectrometry – K. Hörr, C. Ruff, B. Weckerle, T. König and P. Schreier – J. Agric. Food Chem., 2001, 49, 21-25.

3. Lack of Discriminating Analytical Methodology

A number of chemical reactions involved in the natural production of flavouring ingredients lack a discriminating analytical methodology. Typical representatives of this group are:

3.1. Ester Hydrolysis

The oxygen in the alcohol moiety originates from a natural plant material (e.g. (*Z*)-3-hexenol from the naturally abundant esters in *Mentha arvensis* oil) and therefore it is **for the time being** quasi-impossible to discriminate between a natural hydrolysis process and a non-natural one.

As far as the acid moiety is concerned, EFFA feels that the scrambling of both the oxygen and the hydrogen is highly dependent on the isotopic composition and amount of water used in the reaction and it is not currently possible to make a clear differentiation between a natural process (enzymatic hydrolysis or physical process) and a chemical hydrolysis.

3.2. Esterification

EFFA felt that it is even more difficult to discriminate between natural esters obtained by enzymatic esterification and autocatalytic processes and the same esters **from exactly the same raw materials** obtained using non-approved acid catalysis.

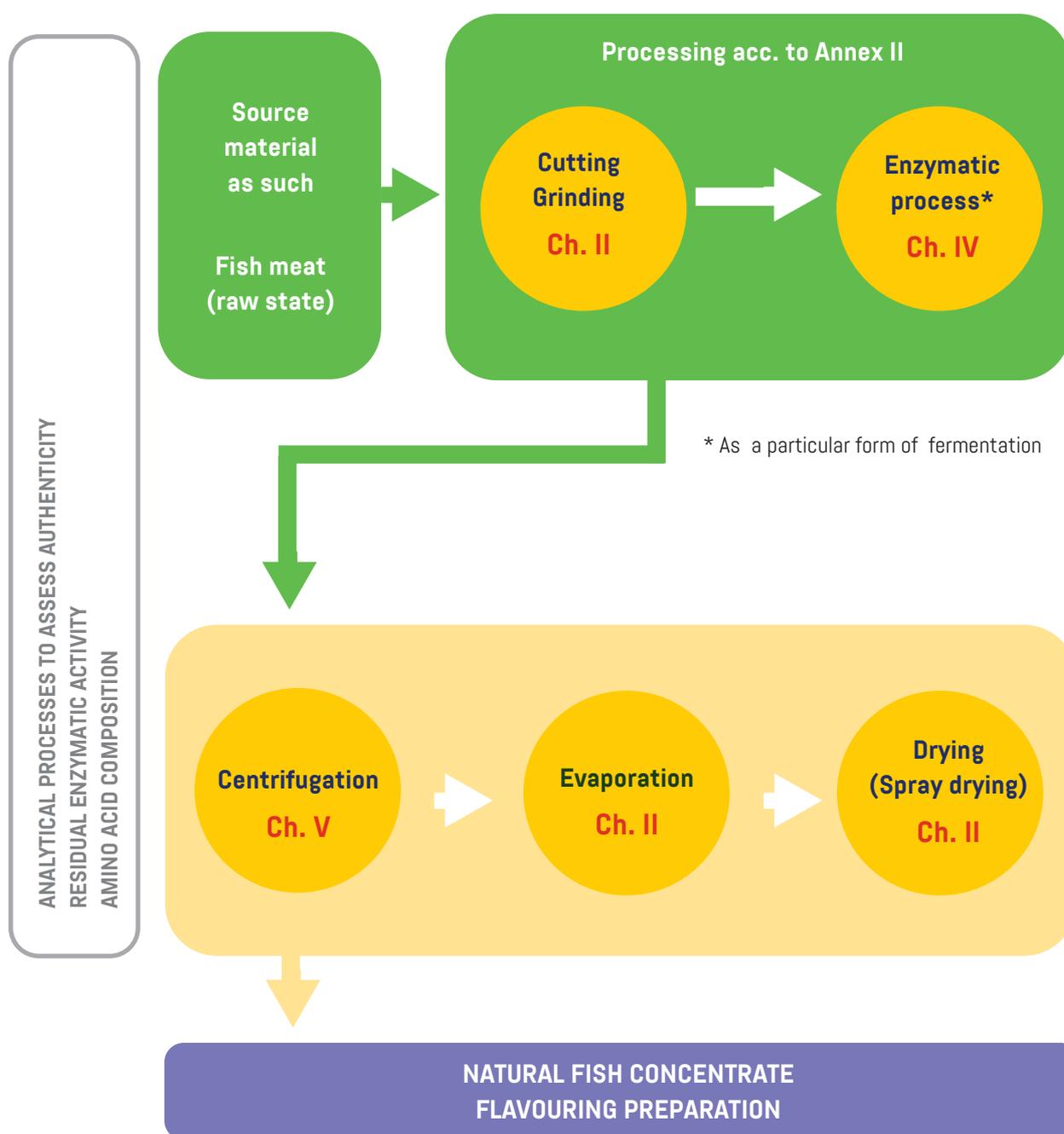
Original version, 03/09/10

Revised version (V2.0), 11/03/13

Revised version (V3.0) 29/09/2016

ATTACHMENT IIc Examples

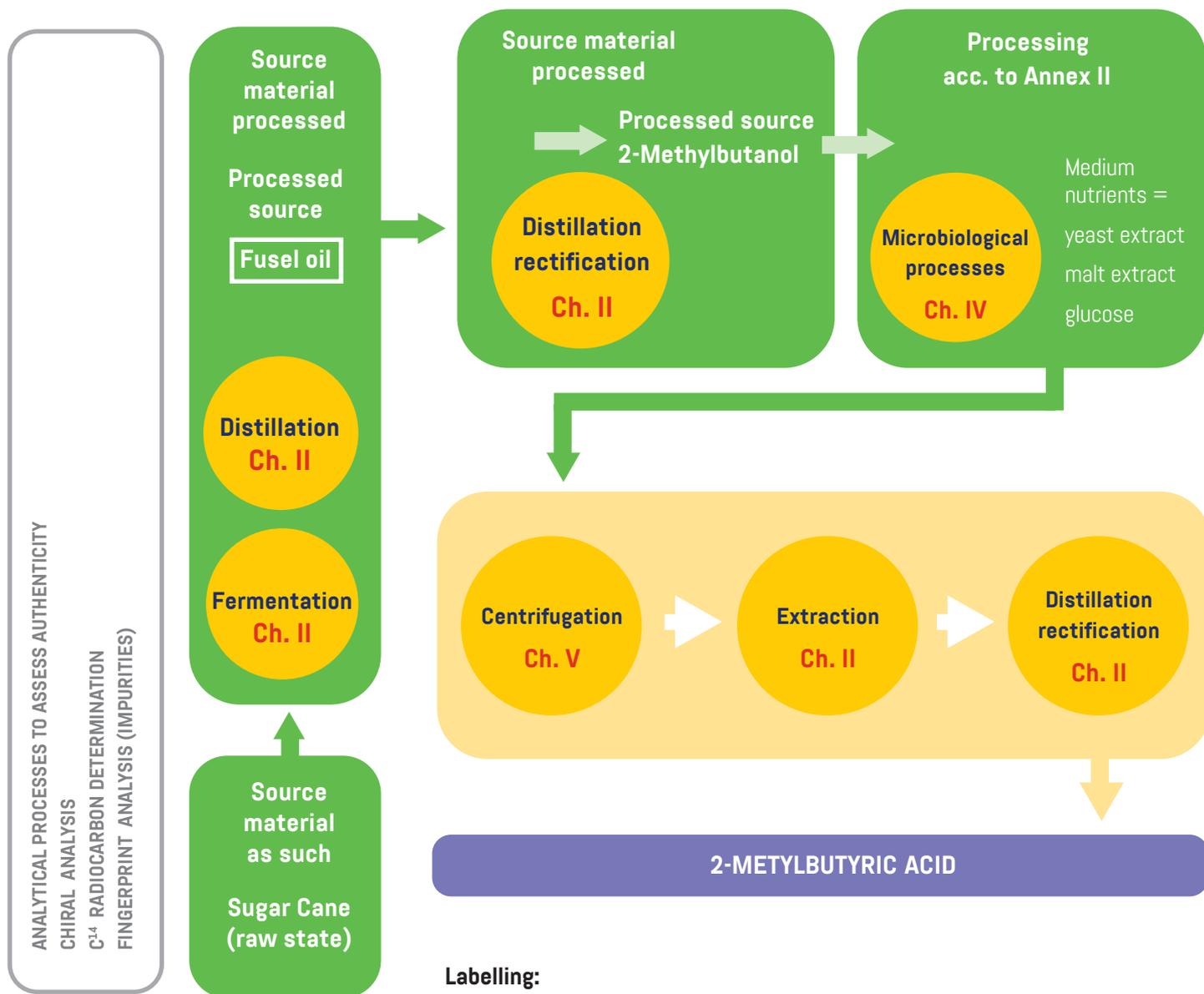
Example 1: Natural Flavouring: Fish Extract



Example 2: Natural Flavouring: Cooked onion extract



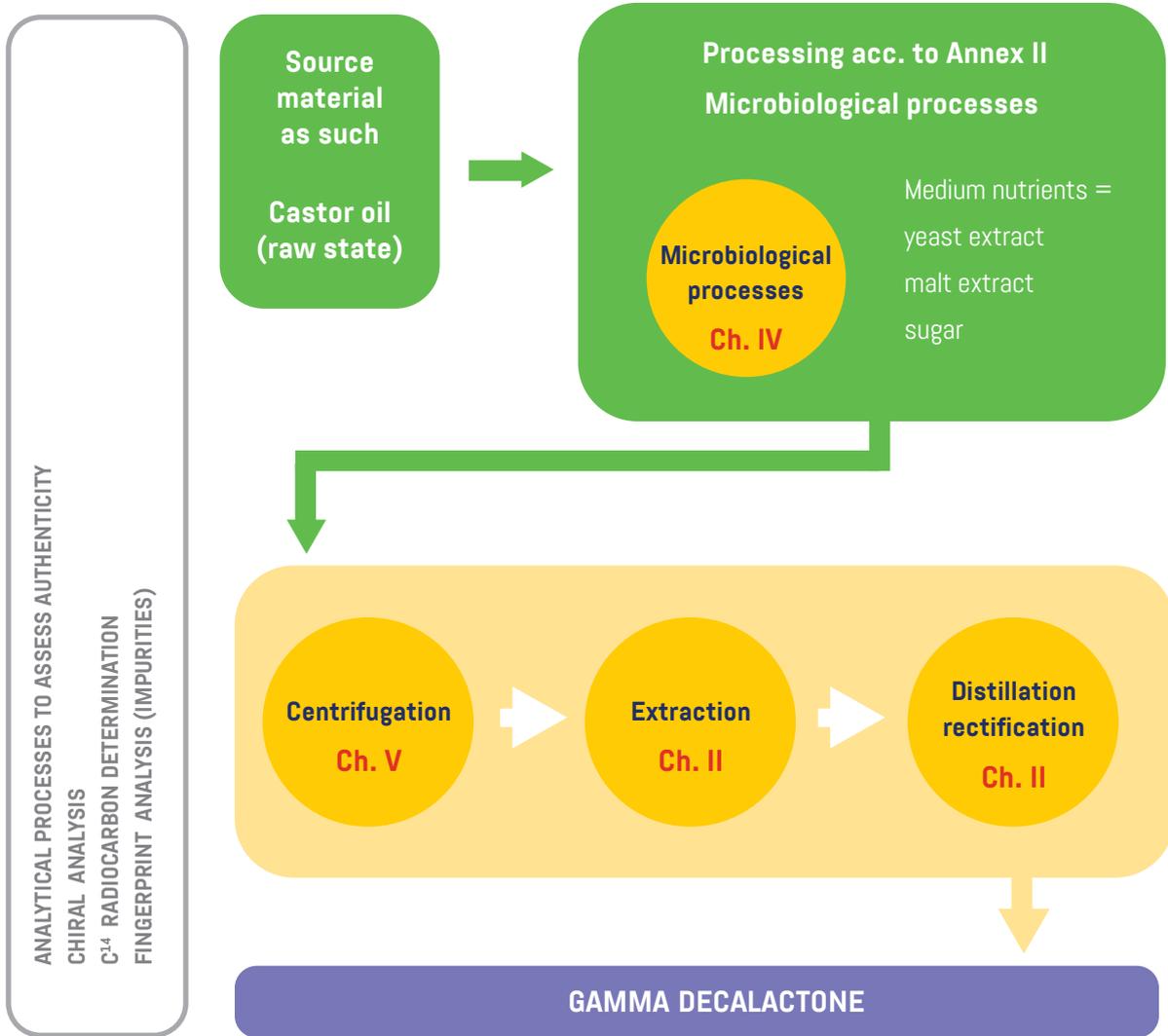
Example 3: Natural Flavouring: Methyl Butyric Acid



Labelling:

Natural 2-Methylbutyric Acid
Natural flavouring substance

Example 4: Natural Flavouring: Gamma Decalactone



Labelling:

Natural Gamma Decalactone

Natural flavouring substance

ATTACHMENT III

EFFA Information Letter FL/12/07 on the Publication of the Union List

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 20th 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 Article 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 Article 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.

EFFA secretariat – 2 October 2012

ATTACHMENT IV

New EU Regulation for flavourings – Examples of labelling of flavourings

A. Examples of Natural labelling

[Natural <<X>> flavouring – section 3.1.1]		
Flavouring component (only contains natural flavouring substances)	Natural Labelling	Labelling [alternative options – section 3]
<ul style="list-style-type: none"> 95% b/w natural flavouring substances derived from mint (e.g. menthol ex arvensis). 5% b/w substances derived from orange (e.g. limonene ex orange) which is used to introduce a special note 	'Natural flavouring substances' or 'Natural mint flavouring'	'Flavouring' or 'Mint flavouring'
<ul style="list-style-type: none"> 94% b/w natural flavouring substances derived from mint (e.g. menthol ex arvensis). 6% b/w natural flavouring substances derived from apple (e.g. an acid) which is used to adjust natural variations. 	'Natural flavouring substances' or 'Natural mint flavouring with other natural flavourings'	'Flavouring' or 'Mint flavouring'
<ul style="list-style-type: none"> 100 % b/w natural flavouring substances derived from apple and/or raspberry and/or orange Apple, raspberry and orange are not recognizable in the overall flavour profile, which is banana 	'Natural flavouring substances" or 'Natural flavouring'	'Flavouring' or 'Banana flavouring'
<ul style="list-style-type: none"> 100% b/w menthol 	'Natural flavouring substances' or 'Natural flavouring substances (menthol)'	'Flavouring' or 'Mint flavouring' or 'Menthol'

[Natural <<X>> flavouring – section 3.1.2]

Flavouring component (only contains natural flavouring substances and/or flavouring preparations)	Labelling	Labelling [alternative options – section 3]
<ul style="list-style-type: none"> 95% b/w flavouring preparations and/or natural flavouring substances derived from mint (e.g. mint oil and/or menthol ex arvensis). 5% b/w derived from other natural sources (e.g. orange oil or limonene ex orange) which is used to introduce a special note 	'Natural mint flavouring'	'Mint flavouring' or 'Flavouring'
<ul style="list-style-type: none"> 97% b/w flavouring preparations and/or natural flavouring substances derived from raspberry (e.g. raspberry distillate and raspberry isolate). 3% b/w derived from other natural sources (e.g. natural flavouring substances used to adjust natural variations). 	'Natural raspberry flavouring'	'Raspberry flavouring' or 'Flavouring'
<ul style="list-style-type: none"> 55% b/w flavouring preparations and/or natural flavouring substances derived from orange 40% b/w derived from tangerine 5% b/w derived from other natural sources (e.g. strawberry distillate and/or natural flavouring substances) which is used to add a special note 	Natural orange & tangerine flavouring' or 'Natural citrus flavouring'	'Orange & tangerine flavouring' or 'Citrus flavouring' or 'Flavouring'
<ul style="list-style-type: none"> 97% b/w flavouring preparations and/or natural flavouring substances derived from lemon, and recognizable as 'lemon'. 3% b/w derived from other natural sources and introducing an additional caramel note 	'Natural lemon flavouring'	'Lemon & caramel flavouring' or 'Flavouring'

[Natural <<X>> flavouring with other natural flavourings – section 3.1.3]

Flavouring component (only contains natural flavouring substances and/or flavouring preparations)	Labelling	Labelling [alternative options – section 3]
<ul style="list-style-type: none"> 94% b/w flavouring preparations and/or natural flavouring substances derived from mint (e.g. mint oil and/or menthol ex arvensis). 6% b/w from other natural sources (e.g. orange oil or limonene ex orange) which is used to introduce a special note 	'Natural mint flavouring with other natural flavourings'	'Mint flavouring' or 'Flavouring'
<ul style="list-style-type: none"> 50% b/w flavouring preparations and/or natural flavouring substances derived from orange 40% b/w derived from tangerine 10% b/w derived from other natural sources (e.g. strawberry distillate and/or a natural flavouring substance) which is used to add a special note 	'Natural orange and tangerine flavouring with other natural flavourings' or 'Natural citrus flavouring with other natural flavourings'	'Raspberry flavouring' or 'Flavouring'
<ul style="list-style-type: none"> 30% b/w flavouring preparations and/or natural flavouring substances derived from cinnamon 70% derived from other natural sources The cinnamon note is easily recognizable. 	'Natural cinnamon flavouring with other natural flavourings'	'Flavouring' or 'Cinnamon flavouring'

[Natural flavouring – section 3.1.4]

Flavouring component (only contains natural flavouring substances and/or flavouring preparations)	Labelling	Labelling [alternative options – section 3]
<ul style="list-style-type: none"> 0% b/w flavouring preparations and/or natural flavouring substances derived from banana 100% b/w derived from other natural sources (e.g. strawberry, raspberry, etc). The overall flavour-profile is 'banana' 	'Natural flavouring'	'Flavouring' or 'Banana flavouring'
<ul style="list-style-type: none"> 10% b/w flavouring preparations and/or natural flavouring substances derived from banana 90% b/w derived from other natural sources (e.g. strawberry, raspberry, etc). The overall flavour-profile is 'banana' which comes from the other 90% of the source materials. 	'Natural flavouring'	'Flavouring' or 'Banana flavouring'
<ul style="list-style-type: none"> 20% b/w flavouring preparations and/or natural flavouring substances derived from hazelnut 80% b/w derived from other natural sources (e.g. strawberry, raspberry, etc). The overall flavour-profile is 'hazelnut' which comes from the other 80% of the source materials. 	'Natural flavouring'	'Flavouring' or 'Hazelnut flavouring'
<ul style="list-style-type: none"> 100% b/w flavouring preparations and/or natural flavouring substances derived from yeast (e.g. a blend of yeast extracts) The overall flavour-profile is 'chicken'. 	'Natural flavouring'	'Flavouring' or 'Chicken flavouring'
<ul style="list-style-type: none"> 100% b/w flavouring preparations and/or natural flavouring substances derived from fruits The overall flavour-profile is 'grenadine' 	'Natural flavouring'	'Flavouring' or 'Grenadine flavouring'

B. Examples of Labelling Smoke flavourings*

[Labelling of Smoke flavourings – section 2.3.1]

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

* NOTE: The rules for the labelling of 'smoke flavourings' are only found in article 29 'designation of flavourings in the list of ingredients' and therefore relate to final food labelling (see EFFA Guidance Document section 2.3.1)

¹ 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 recital (27)).

ATTACHMENT V

Flow chart for labelling of flavourings (03/09/2010)

The flow chart below is a simplified tool for operators and is for clarification purposes only; it should be read in conjunction with the EFFA Guidance Document (Chapter IV).



¹ 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.

ATTACHMENT VI

Flavour wheels

NATURAL <X> FLAVOURING

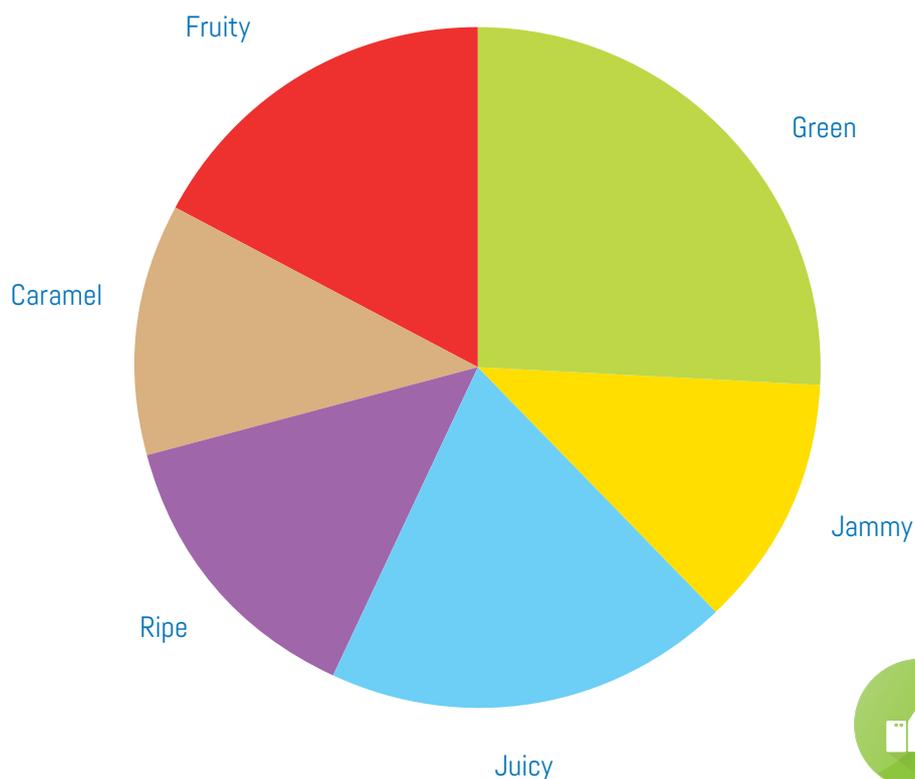
1. Basics

- According to Article 16.2 the flavouring component may comprise only flavouring preparations and/or natural flavouring substances.
- According to Article 16.4 the term 'natural' may only be used in combination with a reference to 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*'.
- *Recital (26):*

'Specific information requirements should ensure that consumers are not misled concerning the source material used for the production of natural flavourings. In particular, if the term natural is used to describe a flavour, the flavouring components used should be entirely of natural origin. In addition, the source of the flavourings should be labelled, except when the source materials referred to would not be recognised in the flavour or taste of the food. If a source is mentioned, at least 95 % of the flavouring component should be obtained from the material referred to. As the use of flavourings should not mislead the consumer, the other maximum 5 % can only be used for standardization or to give a, for example, more fresh, pungent, ripe or green note to the flavouring...'

NATURAL STRAWBERRY FLAVOURING

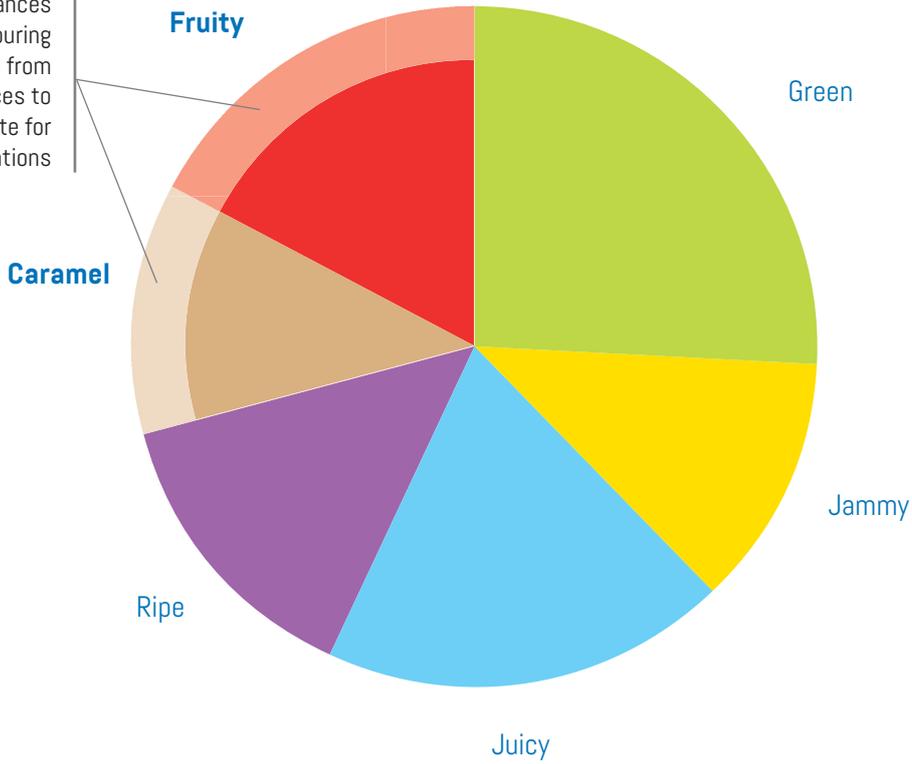
100 % DERIVED FROM STRAWBERRY



NATURAL STRAWBERRY FLAVOURING 95/5

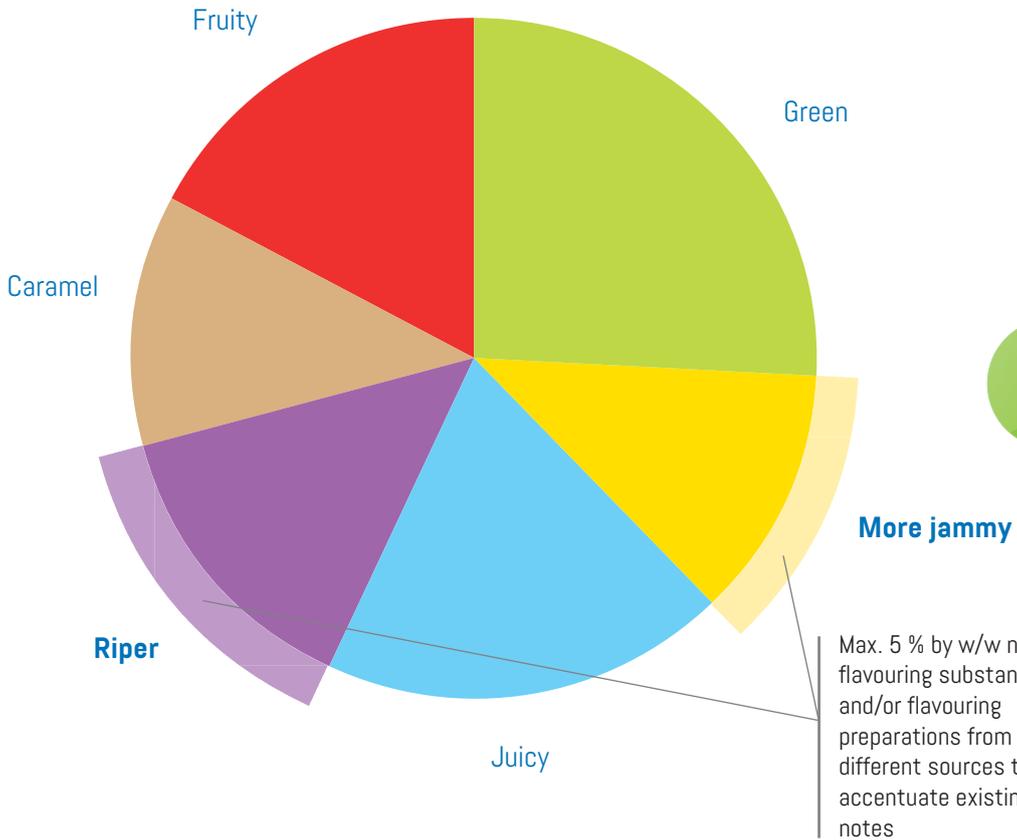
STANDARDISATION

Max. 5 % by w/w natural flavouring substances and/or flavouring preparations from different sources to compensate for crop variations



NATURAL STRAWBERRY FLAVOURING 95/5

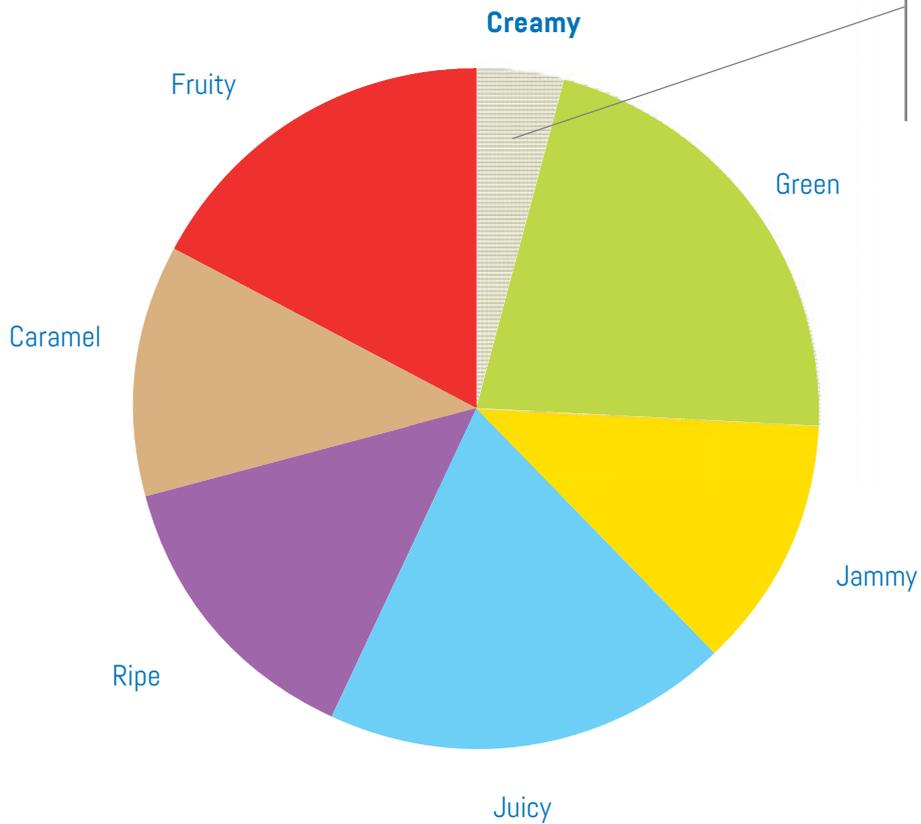
CHARACTERISATION / EXISTING NOTES



Max. 5 % by w/w natural flavouring substances and/or flavouring preparations from different sources to accentuate existing notes

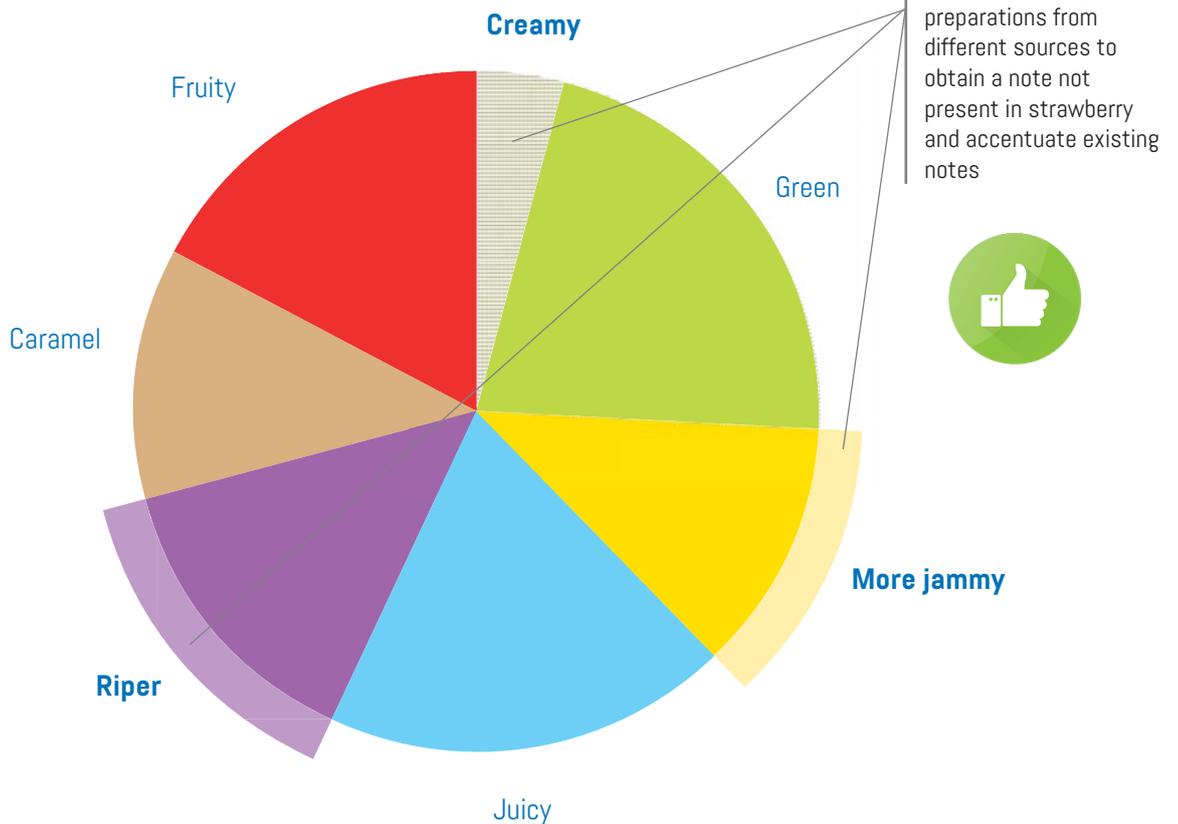
NATURAL STRAWBERRY FLAVOURING 95/5

CHARACTERISATION / NEW NOTES



NATURAL STRAWBERRY FLAVOURING 95/5

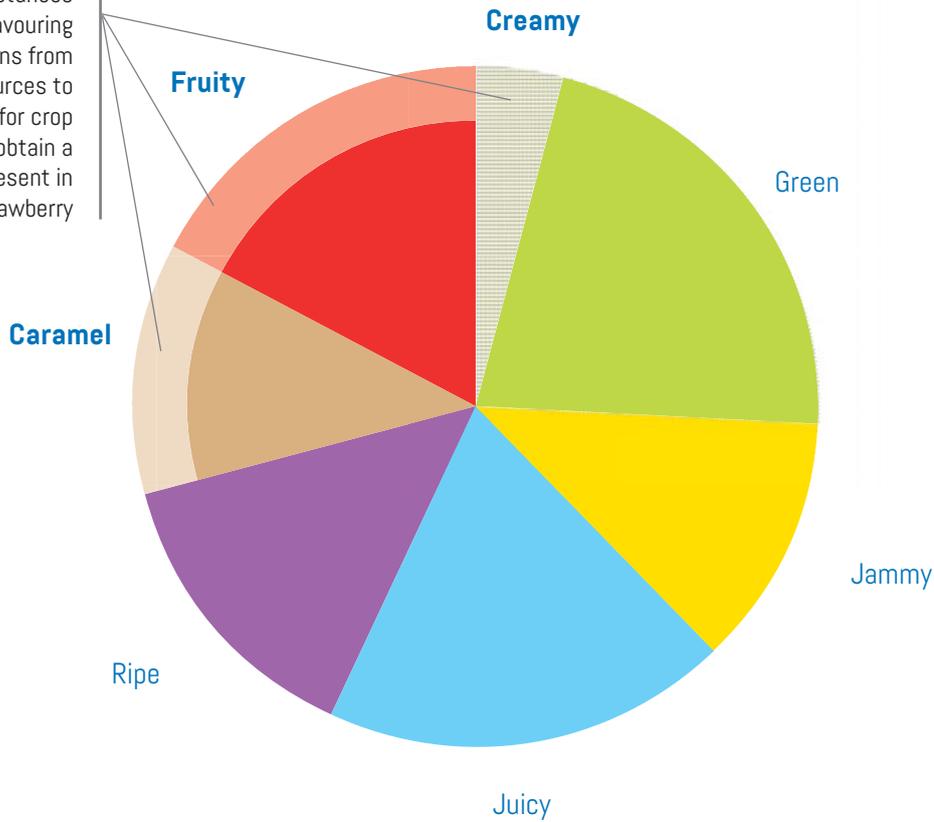
CHARACTERISATION / EXISTING AND NEW NOTE(S)



NATURAL STRAWBERRY FLAVOURING 95/5

STANDARDISATION AND CHARACTERISATION

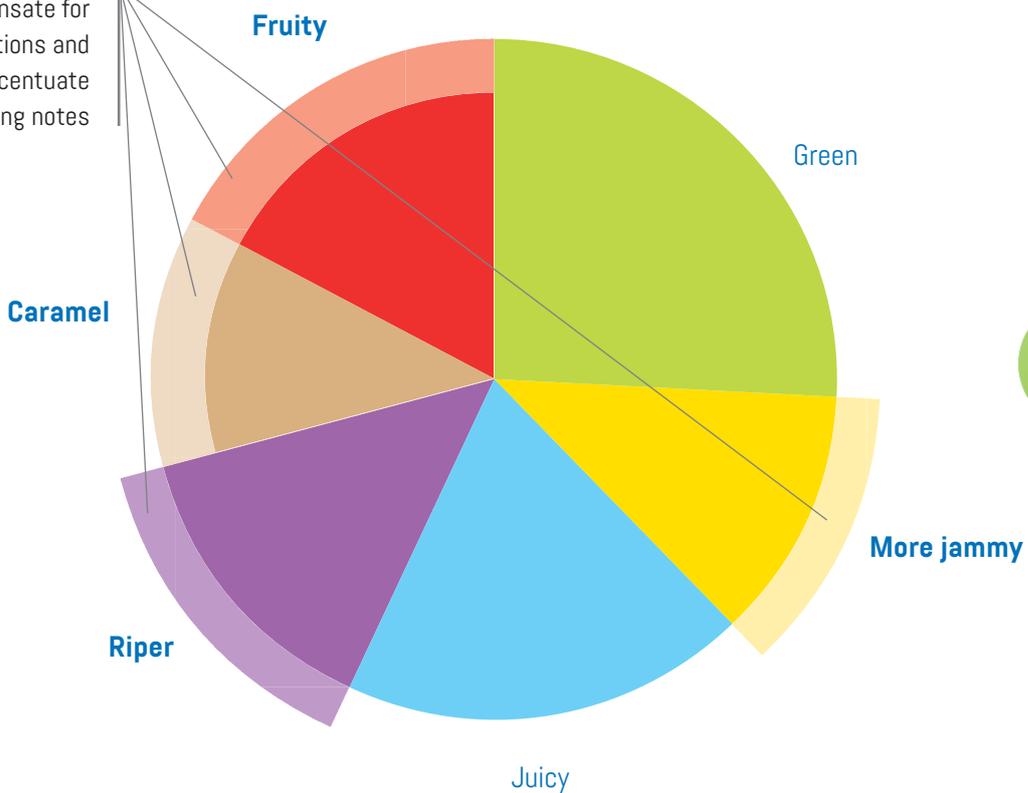
Max. 5 % by w/w natural flavouring substances and/or flavouring preparations from different sources to compensate for crop variations and obtain a note not present in strawberry



NATURAL STRAWBERRY FLAVOURING 95/5

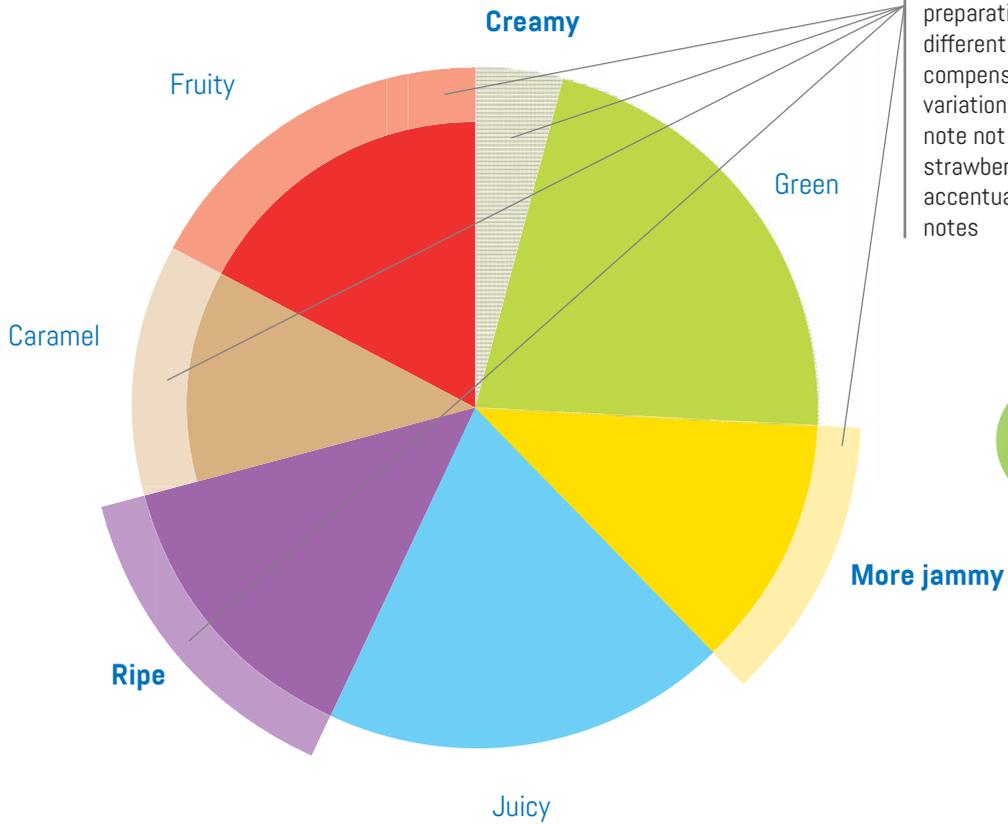
STANDARDISATION AND CHARACTERISATION

Max. 5 % by w/w natural flavouring substances and/or flavouring preparations from different sources to compensate for crop variations and accentuate existing notes



NATURAL STRAWBERRY FLAVOURING 95/5

STANDARDISATION AND CHARACTERISATION

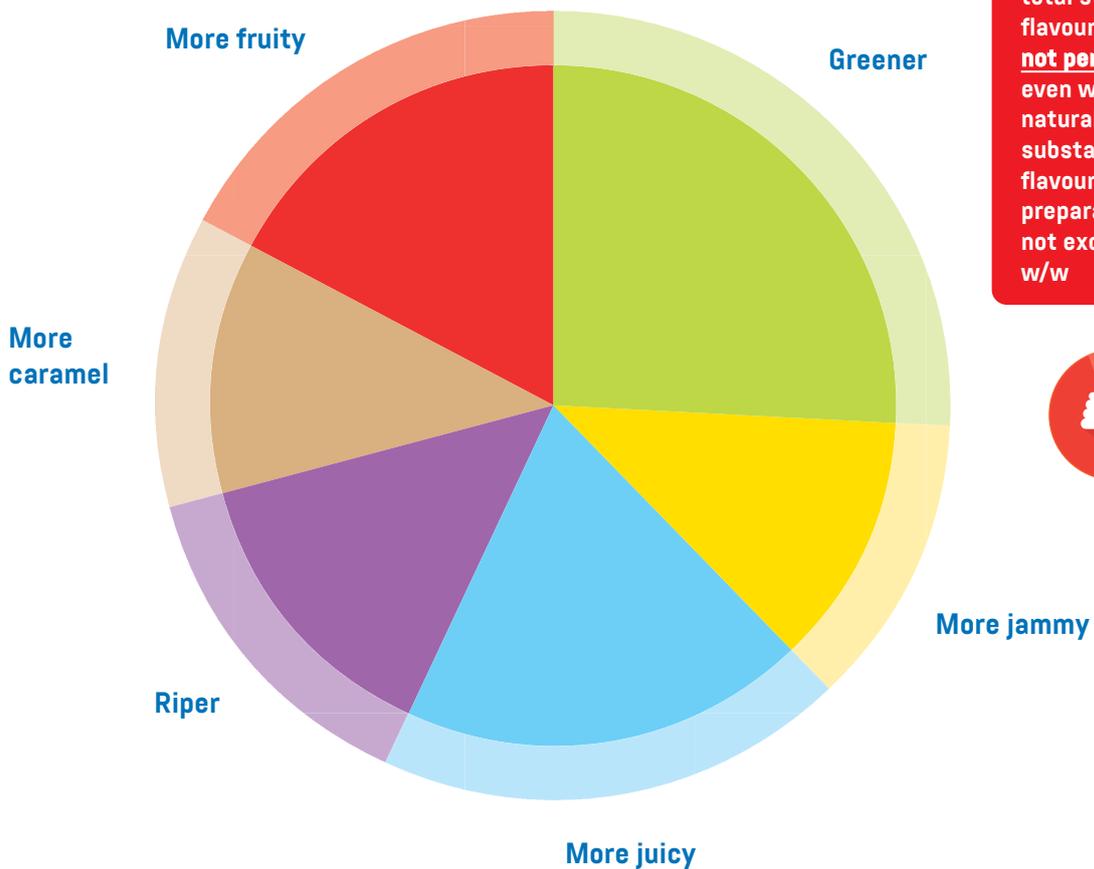


Max. 5 % by w/w natural flavouring substances and/or flavouring preparations from different sources to compensate for crop variations and obtain a note not present in strawberry and accentuate existing notes



NATURAL STRAWBERRY FLAVOURING 95/5

REPRODUCTION



Use of the „5%-part“ to reproduce the total strawberry flavour profile is **not permitted** even when added natural flavouring substances/ flavouring preparations do not exceed 5 % w/w



ATTACHMENT VII

Information Letter IL/13/03 on Time Lines & Transitional Periods of the Union List

The Implementing Regulation establishing the List of Flavouring Substances (Part A of the Union List) has entered into Force and will apply as of 22 April 2013. However, there is a transitional period of 18 months until 22 October 2014, for compliance with all requirements: from this day all provisions stipulated in the Implementing Regulation and the List of Flavouring substances will apply. The application Date for Part B-F of the Union List is 22 October 2016.

Adoption, Publication, Entry into Force and Application of the Regulations

- The Regulations in relation to the Union List (as formally adopted on 1 October 2012 and published in the Official Journal on 2 October 2012) entered into Force on 22 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 to Regulation (EC) No 1334/2008* [OJ L 267/162], hereinafter referred to as "Regulation on transitional measures".
- 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**.

Transitional measures and periods for the Union List Part A: Flavouring Substances

- All flavouring substances listed in the Union List Part A may be used throughout the EU in and on food irrespective of footnotes.
- From the date of application of the Implementing Regulation and the Union List Part A (22 April 2013) there is a transitional period of 18 months for compliance with all requirements until 22 October 2014 at which date Article 10 of Regulation (EC) No 1334/2008 applies.
- This means that during this transitional period flavouring substances **not included in the List** may be placed on the market and used in or on food, i.e. **until 22 October 2014**.
- 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**: stocks of foods (including such non-listed flavouring substances) can be sold until their **date of minimum durability (DMD) or use-by date (UBD)**.

- It is our understanding that compounded flavourings are also considered as foods and are covered by the same transitional measures as foods.
- Also all other provisions such as restrictions of use (as indicated in Column 7 of the List for 11 flavouring substances) and compliance with purity requirements (cfr Column 6 of the List) shall apply from **22 October 2014** (i.e. Application of Article 10 of Regulation (EC) No 1334/2008).
- From **22 October 2014** (application date of Article 10) only those substances that are listed on the UL Part A can be used in or on food to the exclusion of all other substances.

Transitional measures and periods for the Union List Part B-F: Flavourings & Source Materials (SM)

- This section applies only to those flavourings & SM which require an evaluation and approval according to Article 9 (b) to (f) of the Flavouring Regulation (EC) No 1334/2008:
 - (b) flavouring preparations referred to in Article 3(2)(d)(ii) of that Regulation;
 - (c) thermal process flavourings obtained by heating ingredients which fall partially or totally within Article 3(2)(e)(ii) and/or for which the conditions for the production of thermal process flavourings and/or the maximum levels for certain undesirable substances set out in Annex V are not met;
 - (d) flavour precursors referred to in Article 3(2)(g)(ii);
 - (e) other flavourings referred to in Article 3(2)(h);
 - (f) source materials other than food referred to in Article 3(2)(j)(ii).
- For flavourings and SM that were **legally placed on the market** at the time of entry into force of the regulation on transitional measures (i.e. 22 October 2012), the time window for submission of dossiers for evaluation by EFSA is until 22 October 2015.
- **New** flavourings & SM (i.e. those which were not placed on the market before the entry into force date (i.e. 22 October 2012)) can only be introduced onto the market after pre-market approval which requires the submission of a valid dossier (according to the Common Authorisation Procedure – CAP (Regulation (EC) No 1331/2008)), evaluation by EFSA and authorisation by the Commission.
- Parts B to F of the Union List of Flavourings & SM shall apply from **22 October 2016**.
- This means that flavourings & SM **not included in the List Part B-F** may be placed on the market and used in or on food **until 22 October 2016**.
- From **22 October 2016** (application date of UL Part B-F) only those flavourings & SM that are included in the UL Part B-F can be used in or on food to the exclusion of all others.
- Foods containing flavourings & SM 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**.

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.



Annex (Attachment VIII): Time line charts
(page 1: UL Part A – page 2: UL Part B-F)

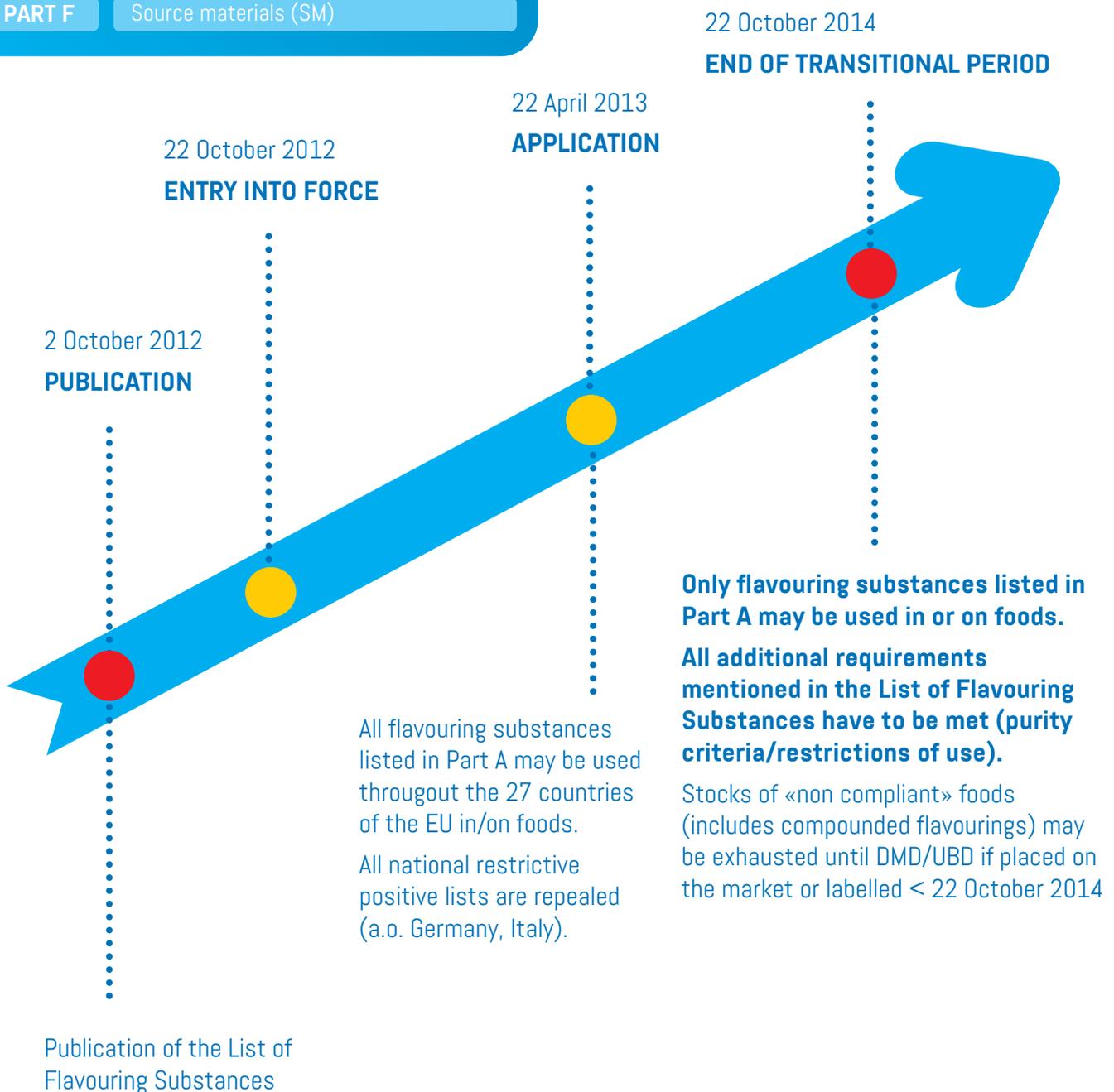
EFFA Secretariat – 6 March 2013

ATTACHMENT VIII

Time Line Charts of the Union List

ANNEX 1	
PART A	Flavouring substances
PART B	Flavouring preparations
PART C	Thermal process flavourings
PART D	Flavour precursors
PART E	Other flavourings
PART F	Source materials (SM)

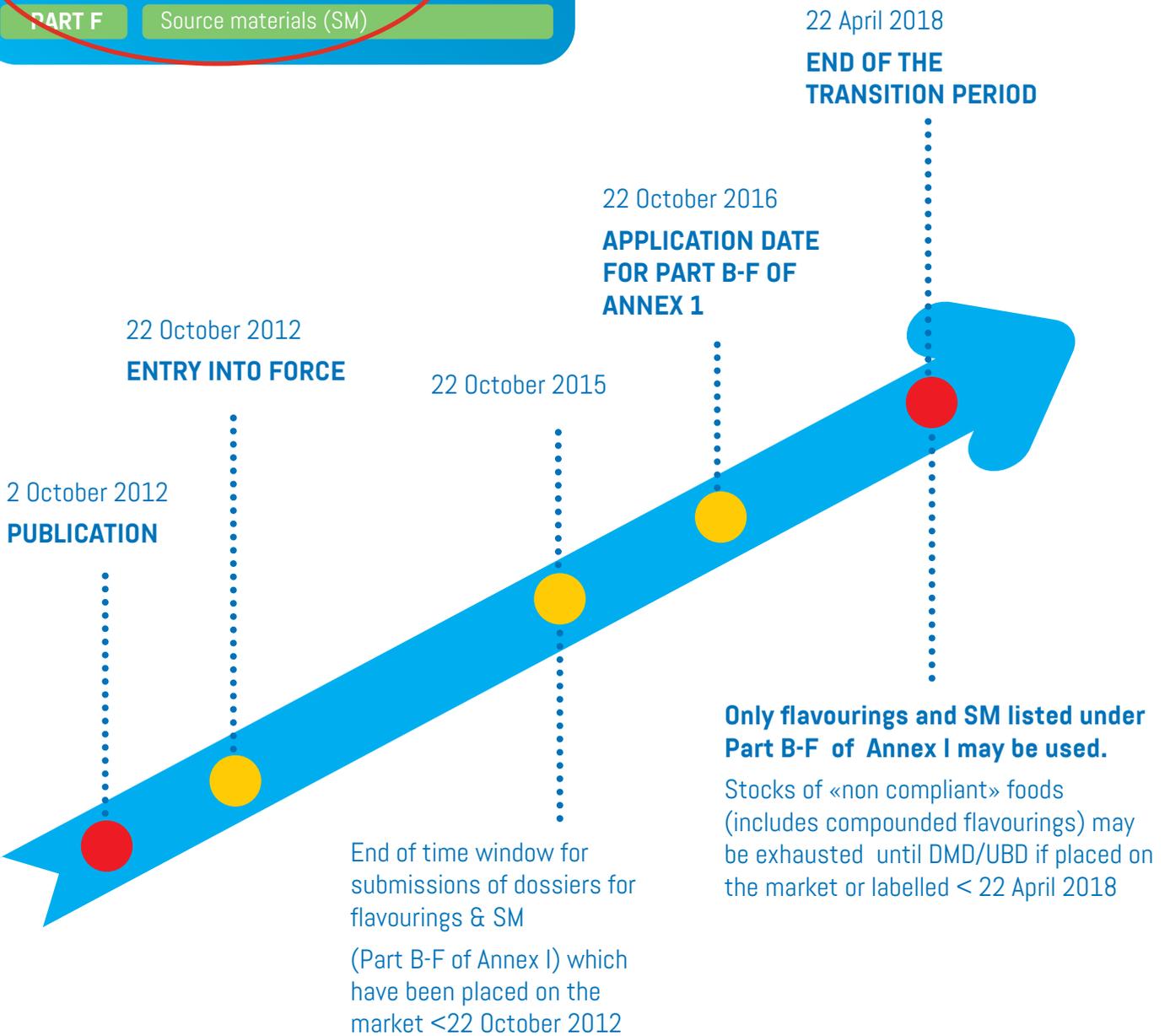
Time line for the Implementing Regulation (EU) N° 872/2012 adopting the List of Flavouring Substances (Part A of Annex I referred to in Regulation (EC) N° 1334/2008)



ANNEX 1

PART A	Flavouring substances
PART B	Flavouring preparations
PART C	Thermal process flavourings
PART D	Flavour precursors
PART E	Other flavourings
PART F	Source materials (SM)

Time line for Regulation (EU) N° 873/2012 on transitional measures for Annex I Part B-F of the Union List referred to in Regulation (EU) N° 1334/2008



Commission Guidance notes on the classification of a flavouring substance with modifying properties and a flavour enhancer*

IMPORTANT DISCLAIMER

These guidance notes have been produced by the European Commission's DG Health and Consumers with the aim of providing informal guidance for the applicants and they do not necessarily represent the official views of the Commission. This document has no formal legal status and should be read in conjunction with the appropriate legislation. In the event of a dispute, ultimate responsibility for the interpretation of the law lies with the Court of Justice.

The guidance notes have been subject to consultation with the EU Member States' experts on flavourings and the relevant stakeholders.

1. Purpose

The purpose of this document is to provide food business operators and competent authorities with criteria in order to distinguish between the use of a chemically defined substance as a flavour enhancer or as a flavouring substance with modifying properties. Such criteria will help the applicants to classify the substances in order to apply for authorisations within the correct legal framework.

Some chemically defined substances have multifunctional properties and can be used for their flavouring purposes (flavouring substance) or for technological purposes (food additive). The legal status of the ingredient depends on its intended functional effect in the final food.

For the purpose of this document the word "enhance" is a synonym for words "intensify, increase, strengthen, amplify".

2. Flavouring substances with modifying properties

Legislative framework:

The term "flavourings" is defined in Article 3, paragraph 2 of Regulation (EC) No 1334/2008¹ on flavourings:

(a) 'flavourings' shall mean products:

(i) not intended to be consumed as such, which are added to food in order to impart or modify odour and/or taste;

So, a flavouring **imparts** odour and/or taste to food or **modifies** odour and/or taste of food.

Substances with **exclusively** sweet, sour or salty taste are excluded from the scope of the Regulation according to Article 2(2)(a).

The term "flavouring substance" is defined in Article 3(2)(b) as "a defined chemical substance with flavouring properties".

'Flavouring substance' is a substance with flavouring properties; flavouring properties are not defined. But it can be interpreted as in Article 3 2(a)(i): imparting or modifying the taste or the odour. The Regulation does not explicitly state that the substance itself should have flavour; therefore, a flavouring substance could be tasteless or odourless. In conclusion a flavouring substance is a defined chemical substance which is added to food to **impart** or **modify** odour and/or taste. Importance is given to for what functional effect the substance is added to food.

*http://ec.europa.eu/food/safety/food_improvement_agents/flavourings/eu_lists_flavourings/index_en.htm

¹OJ 354, 31.12.2008, p.34

The term "flavouring substance with modifying properties" has not been defined in the Regulation but can be interpreted to mean those flavouring substances which modify odour and/or taste of the food.

Article 13(a) and (b) of the Regulation (EC) No 1334/2008 states that the Commission may decide by way of comitology whether or not a given substance falls within the categories listed in Article 2(1) and to which specific category, defined in Article 3(2)(b) to (j), a given substance belongs.

How are flavouring substances with modifying properties used?

Flavouring substances with modifying properties are used to change the individual characteristics of the flavour of a food. Flavour modification effects can include increasing, decreasing, or changing the perception of individual relevant sensorial characteristics of flavour.

For example, in some situations flavouring substances with modifying properties will:

1. impact the time onset and duration of the perception of specific aspects of the flavour profile and/or
2. reduce specific flavour off-notes, for example decrease metallic flavour and/or
3. intensify specific flavour characteristics, for example increase the perceived fruitiness and/or
4. reduce specific flavour characteristics, for example reduce bitterness.

The ability of flavouring substances with modifying properties to modify flavour can be independent of their aromatic or taste characteristics.

- For example, when neohesperidine DC (which at high concentrations tastes sweet) is added to a flavouring which is then added to a food, it is able to increase specific characteristics, such as the perceived fruitiness or jammy character of the flavouring. At the same time, it reduces the perceived bitterness of the food. The perceived change in the overall taste profile of the finished foodstuff is based on the modification of unique flavour profile characteristics and not just an enhancement of the existing flavour profile.

If a modification of sweetness, sourness and saltiness occurs through the use of a flavouring substance with flavour modifying properties, these modifications must not be the primary effect. The primary effect must be at least one of the flavour modifying effects as outlined under bullets 1-4 and must also occur to some significance.

3. Flavour enhancers

Legislative framework:

The definition of "flavour enhancer" is laid down in point 14 of Annex I of Regulation (EC) No 1333/2008² on food additives:

'flavour enhancers' are substances which enhance the existing taste and/or odour of a foodstuff;

Article 3 (2) (a) of the Regulation defines 'food additive' as *'any substance not normally consumed as a food in itself and **not normally used as a characteristic ingredient of food**, whether or not it has nutritive value, the intentional addition of which to food for a technological purpose in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food results, or may be reasonably expected to result, in it or its by-products becoming directly or indirectly a component of such foods';*

Furthermore, Article 3(2) (ii) of the Regulation states which substances are **not** considered to be food additives:

*'foods, whether dried or in concentrated form, including **flavourings** incorporated during the manufacturing of compound foods, because of their **aromatic**, **sapid** or nutritive properties together with a secondary colouring effect;'*

In addition, recital 5 of the Regulation explains further when substances should be considered food additives and when not:

*"...However, substances should not be considered as food additives when they are used for the purpose of **imparting flavour and/or taste** or for nutritional purposes, such as salt replacers, vitamins and minerals. ..."*

Finally, Article 2(2) of Regulation 1333/2008 addresses the issue of a possible overlap in scope between Regulations 1334/2008 and 1333/2008.

Article 2 (2) of Regulation 1333/2008 reads:

"2. This Regulation shall not apply to the following substances unless they are used as food additives:

.../...

(e) flavourings falling within the scope of Regulation (EC) No 1334/2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods."

As the term 'flavour enhancer' is especially listed in Annex I as a "functional class of food additives", it should be considered that these are used as additives and the exclusion mentioned in Article 2(2) (e) is not applicable to them.

If a substance falls under the definition of flavour enhancer, it is not excluded from the additives Regulation and should be authorised as a food additive.

Article 19(c) of the Regulation (EC) No 1333/2008 states that the Commission may decide by way of comitology whether a given substance meets the definition of food additive in Article 3.

How are flavour enhancers used?

Flavour enhancers are added to food:

- to amplify the **existing** taste and/or odour of a foodstuff, and/or
- to increase the overall perception of **all** flavour characteristics, and/or
- to increase a single flavour perception so significantly that it is out of balance relative to the modification of the other flavour characteristics.

For example, monosodium glutamate (E 621) is considered a flavour enhancer as it is enhancing the flavour of proteins. It increases the umami taste in foods such as soups, sauces and savoury snacks.

A substance used as a flavour enhancer does not impart flavour itself but enhances flavour that the food already has through its ingredients or added flavourings.

Therefore, also those substances that mainly enhance sweetness of food through intensifying the taste of added sugars or sweeteners should be considered as flavour enhancers. The intended function of the added substance is to enhance sweet flavour, thus leading to the possibility of reducing the amount of added sweet ingredients. The same approach would apply if the substance is added mainly to enhance the saltiness or sourness of food.

4. Examples of flavour enhancers and flavouring substances with modifying properties

Flavour enhancers

- Monosodium glutamate (E621). It is authorised under Regulation 1333/2008 on additives as a flavour enhancer in many processed foods.

Flavour substances with modifying properties

- Neohesperidine DC when added to a flavouring which is then added to a food to increase specific characteristics, it is able to increase specific characteristics, such as the perceived fruitiness or jammy character of the flavouring. Neohesperidine DC is an authorised flavouring substance under Regulation 1334/2008 at a level of up to 5 mg/kg.

Notes on Neohesperidine DC:

1. Neohesperidine DC (E959) is also a flavour enhancer authorised under Regulation 1333/2008 on additives at a level of up to 5 mg/kg.
2. Neohesperidine DC (E959) is also authorised as a sweetener under Regulation 1333/2008 for uses at levels between 10 to 150 mg/kg.

5. Consequences following the classification

The applicant has to distinguish between 'flavouring substances with modifying properties' and 'flavour enhancers':

- Chemically defined substances that modify the taste and/or the odour of a food are evaluated, authorised and used in accordance with the flavouring Regulation (EC) No 1334/2008 (section 2).
- Chemically defined substances that enhance the existing taste and/or odour of a foodstuff at the intended levels of use, are evaluated, authorised and used in accordance with the food additives Regulation (EC) No 1333/2008 (see section 3).

6. Supporting documents to be provided by the applicant as regards flavouring substances with modifying properties

Sensory profiles should be established by tasting samples with and without the substance for which an application has been made.

This should be done by an expert panel that examines the relative intensity of specific descriptors of odour and taste of some flavoured foods.

Methodology used for training experts and for establishing a sensory profile should be based on ISO International Standards such as:

- ISO 3972: Sensory Analysis- Methodology – General Guidance for establishing a Sensory Profile
- ISO 13299: Sensory Analysis – Methodology – Method of investigating sensitivity of taste

EFFA Guidance on Flavourings with Modifying Properties (FMPs)

Preliminary remarks

The European Commission issued its “*Guidance notes on the classification of a flavouring substance with modifying properties and a flavour enhancer*”, hereinafter referred to as the “Commission Guidance Note”¹ [Attachment IX] on 27 May 2014.

This Commission Guidance Note aims at providing food business operators and competent authorities with criteria in order to distinguish between the use of a chemically defined substance as a flavour enhancer or as a *flavouring substance with modifying properties*. Such criteria shall help the applicants of new chemically defined substances to classify them in order to apply for authorisations within the correct legal framework.

The Commission Guidance Note as well as the EFFA document FL/12/44C [Annex ²] submitted by EFFA in the course of the editorial discussions at EU-level relate to chemically defined substances in the context of their notification. However, it appears that food operators increasingly raise specific questions relating to the correct use and the appropriate labelling of flavourings with modifying properties in general.

The objective of this document is to provide supplemental guidance to the flavouring industry and to the food industry on how to establish the appropriate use of flavourings with modifying properties.

Supplemental guiding elements

One of the key conclusions of the Commission Guidance Note is that the intended functional effect in the final food determines the legal status of the substance under consideration and hence how it will be classified, either as *flavour enhancer* or as *flavouring substance with modifying properties*.

EFFA is however of the opinion that it is the determined “functional / technological effect” in the final food at the intended use level rather than the intended effect that determines under which regulation the ingredient will fall and how it needs to be classified and / or notified.

It is EFFA's understanding that this principle applies to flavourings as a whole and to all flavouring categories as defined by Article 3(2)(a)(i) of the Flavouring Regulation (EC) No 1334/2008 and mixtures thereof. In fact, it is the determined functional effect at the intended use level in the final food that determines the legal status of a given flavouring material or a combination of flavouring materials.

This is moreover important for those products that have a combination of FMPs, combination of which may be assembled by the design of the flavouring, i.e. by the flavouring industry or by the food industry who wishes to combine multiple flavourings.

Definitions and Terminology

The following summary provides an overview of the most relevant definitions and terms used in this document.

Flavourings (as defined according to Article 3(2) of Regulation (EC) No 1334/2008 on flavourings):

- Products not intended to be consumed as such, which are added to food in order to impart or modify odour and / or taste;
- Made or consisting of the following categories: flavouring substances, flavouring preparations, thermal process flavourings, smoke flavourings, flavour precursors or other flavourings or mixtures thereof.

¹ Attachment IX: Commission Guidance notes on the classification of a flavouring substance with modifying properties and a flavour enhancer 27-5-2014

² Annex I: EFFA FL/12/44C Recognition and FMP vs Flavour Enhancer

Substances with exclusively sweet, sour or salty taste are excluded from the scope of the Regulation according to Article 2(2)(a) of 1334/2008/EC.

The regulation does not explicitly state that the corresponding flavouring category itself should have flavour; therefore, a flavouring category could be tasteless or odourless. In conclusion, the definition of flavouring covers all flavouring categories mentioned in the definition which are added to food to impart or modify odour and / or taste.

The term “flavouring with modifying properties” has not been defined in the regulation but can be interpreted to mean those flavouring categories which modify odour and / or taste of the food.

Food additive (as defined according to Article 3(2) of Regulation (EC) No 1333/2008):

- “any substance” not normally consumed as a food in itself and not normally used as a characteristic ingredient of food, whether or not it has nutritive value, the intentional addition of which to food for a technological purpose in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food results, or may be reasonably expected to result, in it or its by-products becoming directly or indirectly a component of such foods”.
- Furthermore according to Recital (5) of Regulation (EC) No 1333/2008, “food additives are substances that are not normally consumed as food itself but are added to food intentionally for a technological purpose described in this Regulation”.

Flavour enhancer (as laid down in point 14 of Annex I of Regulation (EC) No 1333/2008 on food additives):

- “Flavour enhancers” are substances which enhance the existing taste and / or odour of a foodstuff.

For the purpose of this document the word “enhance” is a synonym for the words “intensify, increase, strengthen, amplify”.

Determination of the functional effects

A key aspect in the determination of the functional / technological effect is how the difference between the reference sample (without the material under sensorial evaluation³) and the test sample (with the material under sensorial evaluation at the intended use level) is established by a trained expert panel.

It should be underlined that the result of the sensory testing should be established for at least one representative example of the main food matrices / food categories according to the intended use of the material. This could include the establishment of levels above which the material under evaluation has no longer the functional effect of a flavouring with modifying properties. It should be accepted, that these levels equally apply to all subcategories under the main food category.

If various flavour characteristics are modified (i.e. the modification/change in perception, be it increase or decrease) and where no flavour characteristic is perceived by a trained expert panel as being significantly more intense relative to the others, the material under sensorial investigation would be classified as a flavouring with modifying properties (for graphic explanation see Annex I²).

In order to determine the functional effects of the material under sensorial evaluation its sensory effects should be established using internationally recognized sensory protocols primarily ISO 3972 and 13299, but also ASTM methods such as E 1909-11 and E 2164-08 or the FEMA guidance for sensory testing [see Annex III⁴].

The data analysis of the obtained results shall be established by scientifically accepted statistical methods such as Student's t test or ANOVA analysis (Analysis of Variance).

Two sensory tests should be applied:

1. In order to determine whether the material is in the scope of the Flavouring Regulation (EC) No 1334/2008 or not it has to be established that the material does not have exclusively a sweet, sour or salty taste⁴.
2. Test the materials or mixture of materials in the desired food matrix/food category. Prior to this sensory analysis the relevant sensory attributes shall be established by the test director. The sensory profile with and without shall be established by recognized statistical methods and the obtained differences plotted in a graph. Annex II⁵ gives a brief overview of how sensory protocols are applied.

³ The “material under sensorial evaluation” can be one of the categories of flavourings as defined by Article 3 (2) of the Flavouring Regulation (EC) No 1334/2008 or mixtures thereof.

⁴ Annex III: This attachment has not been included in this printed version. You can find it here: <http://www.effa.eu/en/publications/guidance-documents>

⁵ Annex II: Sensory Profiling

Subsequently the sensory profile shall be studied to ensure that the overall modification induced by the tested material, in case an increase in sweetness, saltiness or acidity (sourness) occurs, is in balance and the eventual sweetness/saltiness modification is not the primary effect. For general explanation please see attachment 2 EFFA presentation FMP vs FE.

Maximum advised use levels

The maximum advised use level as provided by the Flavour producer is based on the above sensory data set and is the threshold use level which should not be exceeded in order to ensure flavour functionality of the flavouring. If the flavouring is used in combination with another flavouring which may have modifying properties, then this advised use level is no longer applicable and new sensory data shall be established for the combined flavouring.

Where applicable, the maximum advised use level will also consider any restrictions of use in food/food categories as established on the EU Union List of Flavouring Substances for certain flavouring substances⁶.

DISCLAIMER

The present document has been produced by EFFA solely with the aim of providing informal guidance. It should be read in conjunction with the relevant legislation, 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 obligations⁷ 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.

EFFA Secretariat – 4 March 2015

⁶ EU Union List of Flavouring Substances as adopted by Commission Implementing Regulation (EU) No 872/2012.

⁷ All flavourings - either produced from source materials qualified as food or as non-food - have to comply with the general food law (Regulation (EC) No 178/2002).

ANNEX I:



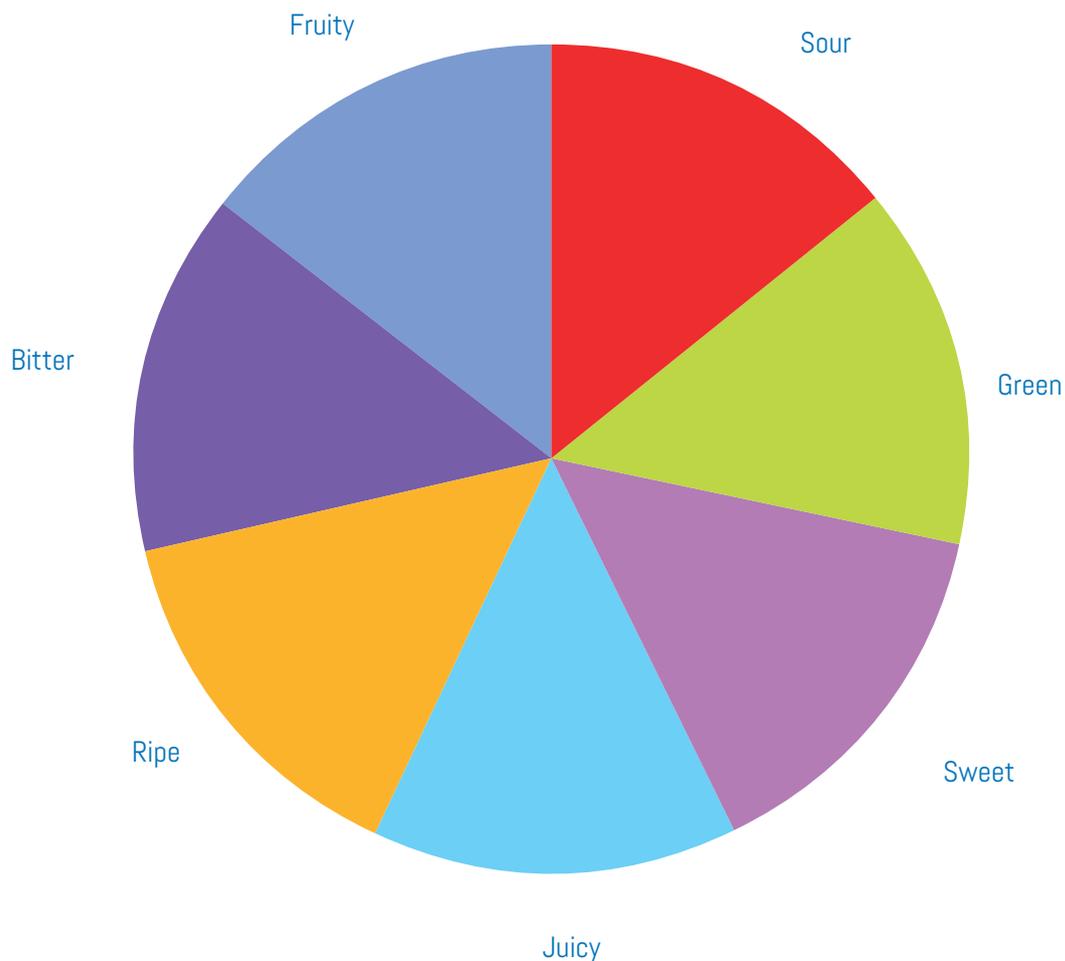
Recognition and FMP vs Flavour Enhancer

Effects of flavouring substances with modifying properties (FMP) vs. effects of flavour enhancers (FE) on sweet and/or sour and/or salt perception

How to demonstrate the classification?

Visualisation of concept

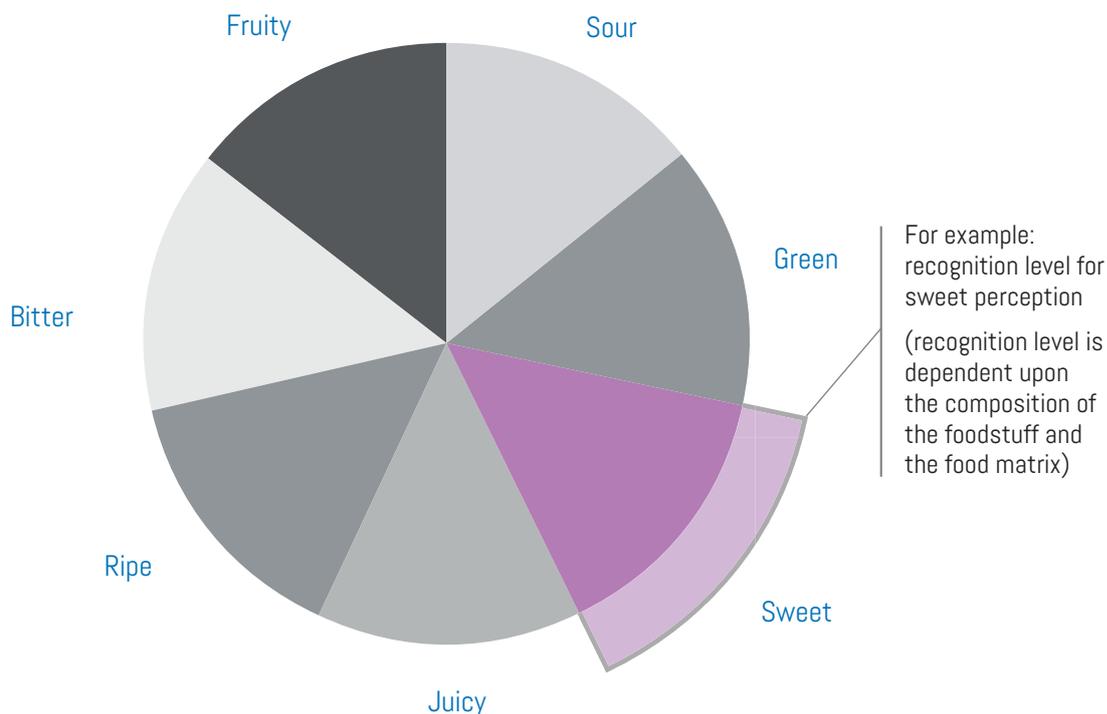
EXISTING FLAVOUR OF FOOD (FLAVOURED OR UNFLAVOURED)



Simplified visualisation of flavour characteristics which can be found in flavoured or unflavoured food

MAIN FOOD CATEGORIES PLUS SUGAR, CITRIC ACID OR SALT AT RECOGNITION LEVEL*

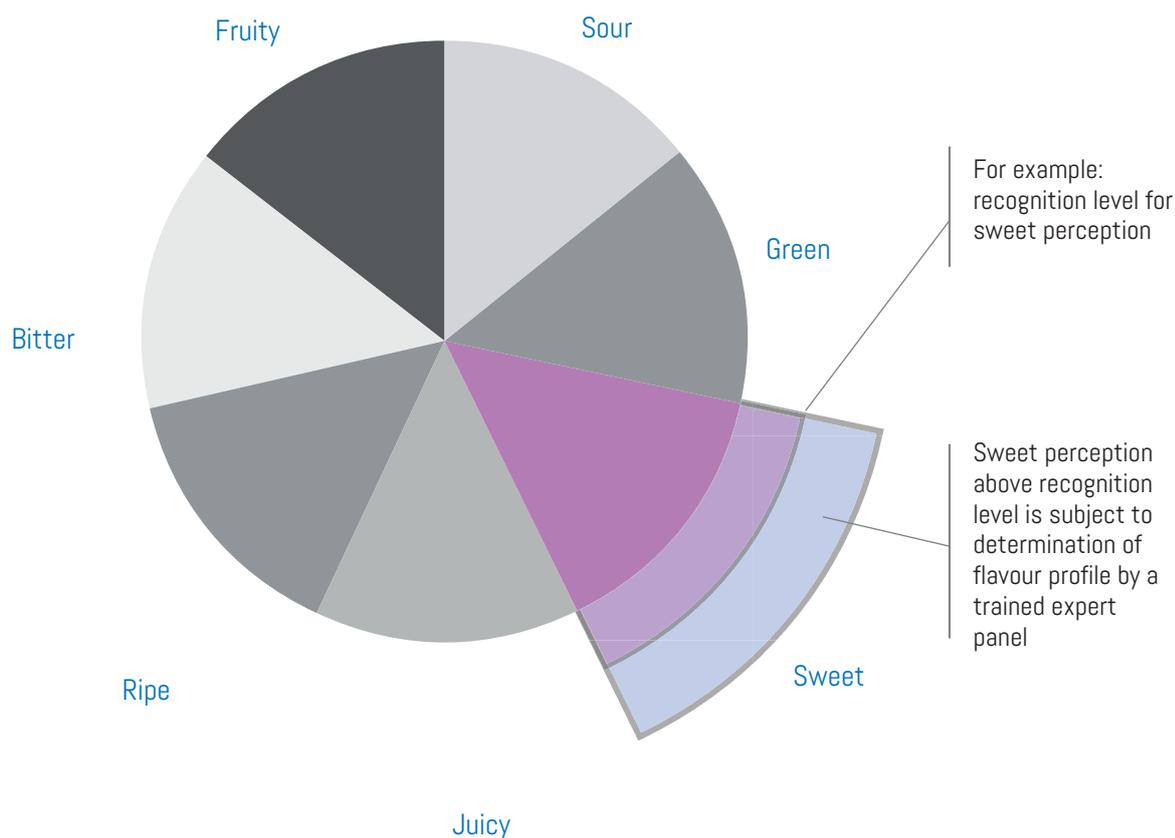
(*At which level is the food recognized as more sweet, more sour or more salty compared to the reference?)



Determination of recognition level in given use level range in selected food matrices according to evolving and established methodology using ISO13299/ISO3972 as a minimum standard.

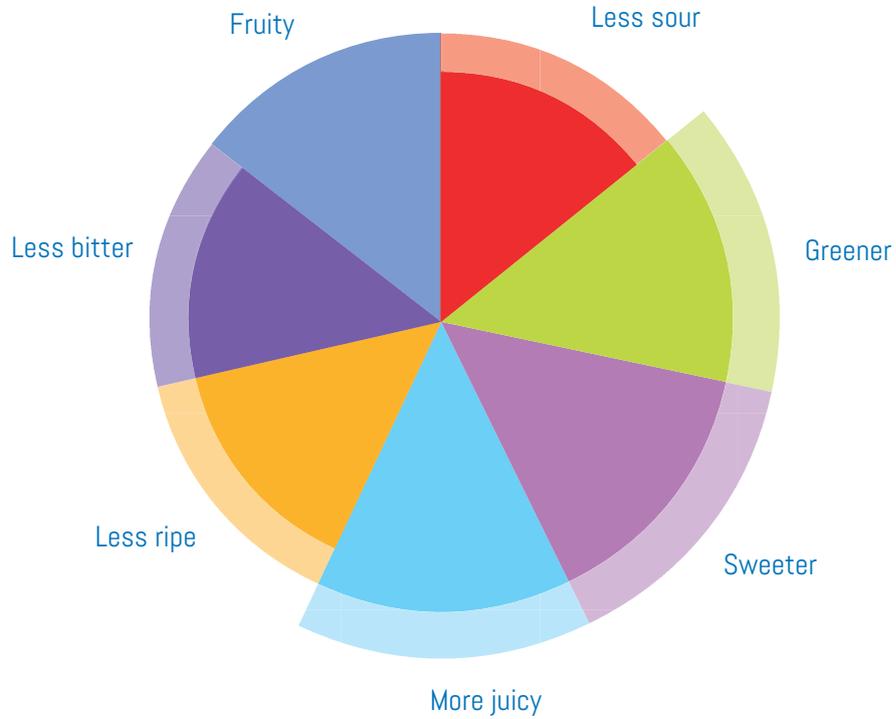
MAIN FOOD CATEGORIES PLUS ADDED SUBSTANCE AT INTENDED USE LEVELS

(At which level is the sweet, sour or salt perception below resp. above recognition level?)



TYPICAL EXAMPLE OF A FOOD WITH A FLAVOURING SUBSTANCE WITH MODIFYING PROPERTIES (FMP)

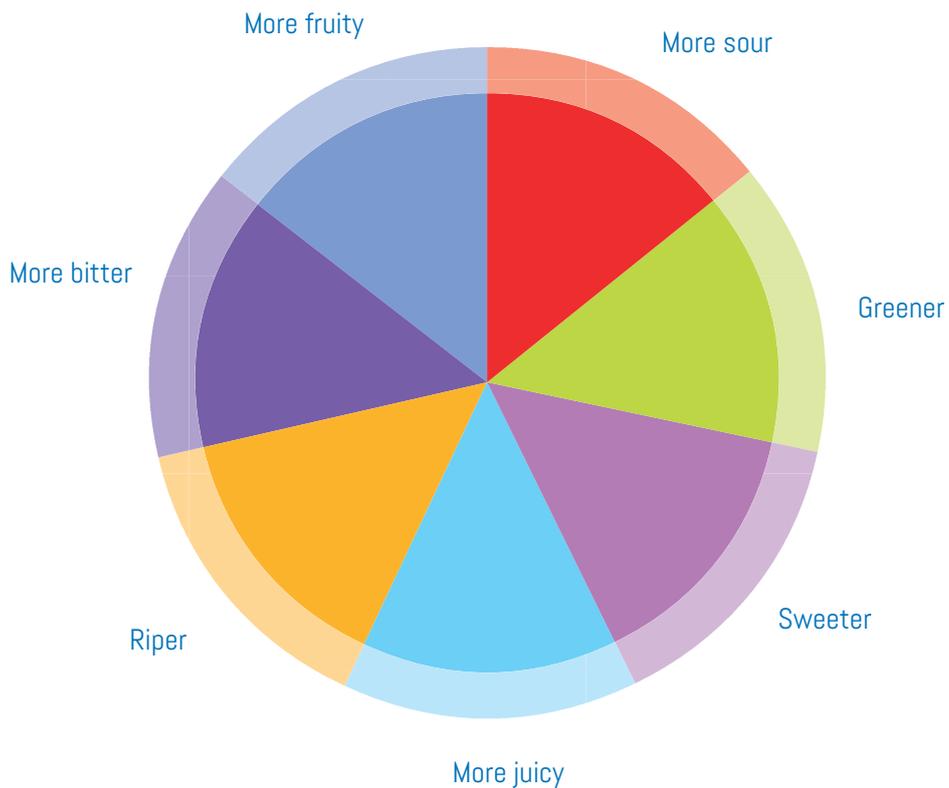
Flavour modification including modulation of sweetness, sourness or saltiness



Determination of flavour profile in given use level range in main food matrices according to evolving and established methodology using ISO13299/ISO3972 as a minimum standard.

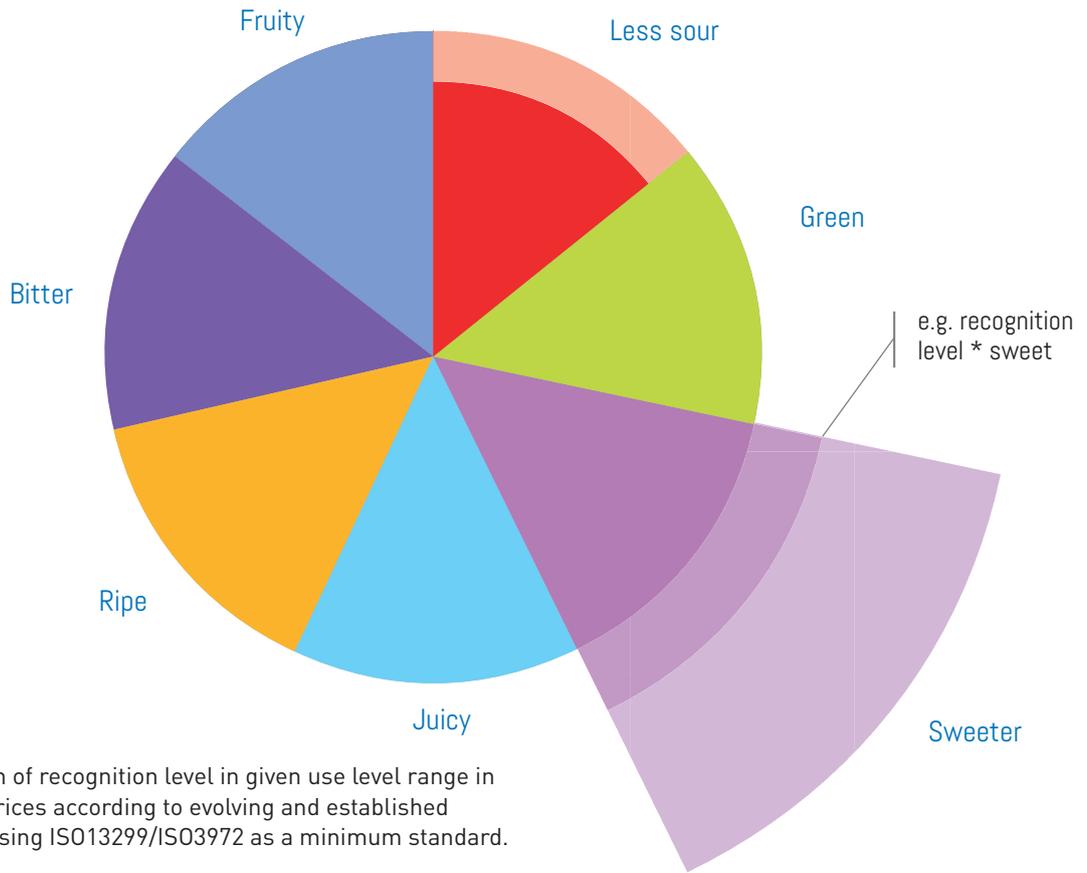
TYPICAL EXAMPLE OF A FOOD WITH A FLAVOUR ENHANCER (FE)

Increase of the overall perception of all flavour characteristics



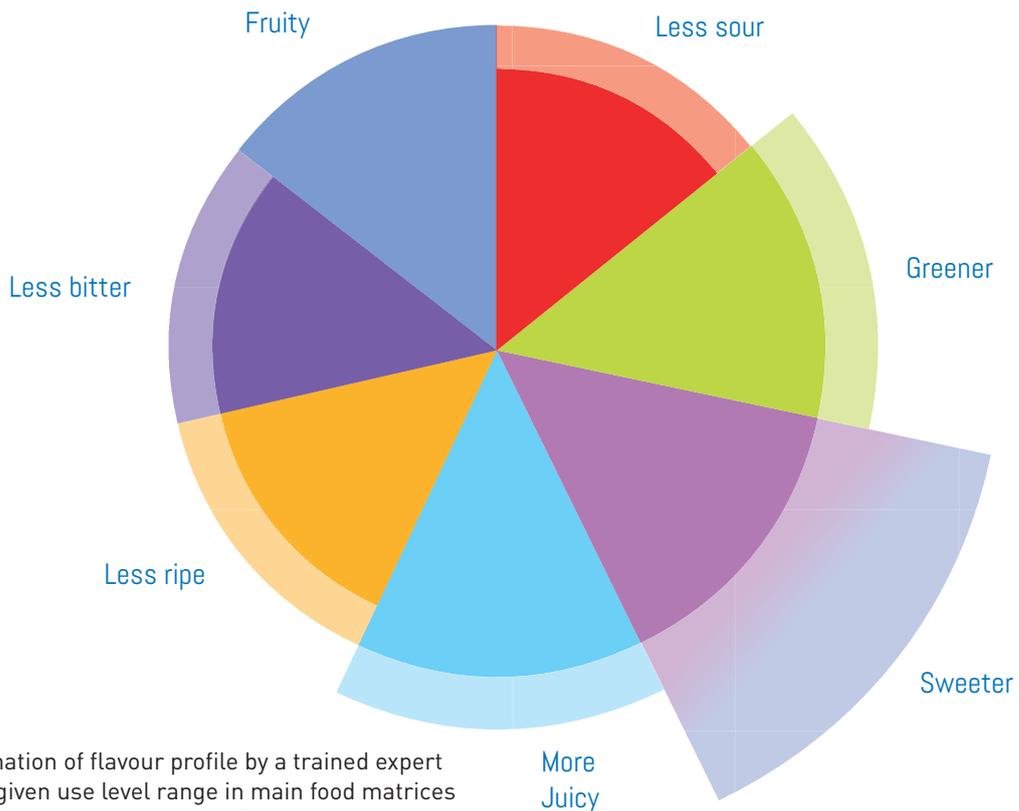
TYPICAL EXAMPLE OF A FOOD WITH A FLAVOUR ENHANCER (FE)

Enhancement of sweetness of food through intensifying the taste of added sugars or intense sweetener (see paragraph 17 of Commission Working Document WGF 12.03.02rev1)



*Determination of recognition level in given use level range in main food matrices according to evolving and established methodology using ISO13299/ISO3972 as a minimum standard.

EXAMPLE OF A FOOD WITH AN ADDED SUBSTANCE WHERE THE SENSORIAL EFFECT REQUIRES EVALUATION BY A TRAINED EXPERT PANEL IN ORDER TO ALLOW FINAL DETERMINATION OF CLASSIFICATION



Determination of flavour profile by a trained expert panel in given use level range in main food matrices according to evolving and established methodology using ISO13299/ISO3972 as a minimum standard.



ANNEX II: Sensory Profiling

This summary describes the overall process for determining a sensory profile. A sensory profile is a descriptive analysis of a sample by a panel of trained assessors. Assessors can be trained and validated using methods as described in ISO 13299 and 3972. Sensory profiling is based on the concept that the overall sensory impression obtained from a sample consists of a number of identifiable sensory attributes (descriptors), each of which is present to a larger or smaller degree. The list of all relevant sensory descriptors, each with its intensity value, is the sensory profile. The descriptors are flavour dependant, i.e. a strawberry flavour will not have the same descriptors as an orange flavour. The latter may e.g. have a “peely” attribute which is not present in strawberries. The panel has been trained to recognize each descriptor by assessing typical molecules or blend of molecules that corresponds to that specific descriptor, like ethyl butyrate for fruitiness.

The procedure is specifically aimed at comparing the sensory profile of one food with that of another or particularly in this case, comparing the sensory profile of a food containing one flavouring with that of the same food containing a different flavouring. This is based on the sensory testing/profiling by a group of assessors using the same list of attributes as described amongst others in ISO 13299 and making comparisons between the samples with statistical analysis.

A maximum of 8 samples are presented in a tasting session. The exact number of samples will depend on their complexity. Several sessions can be organized if more samples need to be evaluated.

An established protocol should be followed by all assessors for rinsing their mouth and cleansing their palate prior to and during evaluations. Assessors should be instructed not to eat, drink and smoke 30 minutes before each evaluation session and to carefully listen to the instructions and carefully read the questionnaires.

The assessors score each sample on a pre-selected set of attributes and scales. The attributes (sensory descriptors) are chosen by the study director from the attributes relevant for the specific flavour.

The procedure summary is as follows:

- The test samples are prepared and identified by a three digit code that is known only to the study director.
- An example of how intensity can be expressed: Assessors assign appropriate intensity ratings for each descriptor on a “0 to 5” structured scale graduated at every half point (and where 0=null, 1=very weak, 2=slightly weak, 3=moderate, 4=slightly strong, 5=strong).
- To increase the reliability of the results, repeat presentations of the same samples can be made (duplication), ideally in a different order and different coding,
- ISO 13299- 2003 defines 8-10 assessors as the minimum assessors in a trained expert panel to establish sensory profiling
- The results from each assessor are combined to give an average and are examined statistically with e.g. ANOVA (Analysis of variance) or student’s t test in order to define significance of differences between each sample for each individual sensory descriptor. For these analyses, the mean intensity scores are statistically compared to determine where significant differences occur. (Statistical significance is established with a confidence level of 90% or 95%). If ANOVA is used a multiple comparison test should be employed to specify the differences among the samples. Data are usually plotted graphically on a spider chart and/or a PCA (Principle Component Analysis) plot.



ATTACHMENT XI

Examples of 'Natural <X> Flavouring'

- **According to Article 16(4) of Flavouring Regulation (EC) No 1334/2008 and Recital (26)**
- **Application of the "95/5-rule"**

- Article 16(2) stipulates that the term 'natural' for the description of a flavouring may only be used if the **flavouring component** comprises only flavouring preparations and/or natural flavouring substances.
- Article 16(4) further qualifies that 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 wording of the Regulation indicates that when considering a "flavouring preparation" – as part of the "flavouring component" of a given "natural <X> flavouring" – in the quantitative determination pursuant to Art. 16(4), the entire "flavouring preparation" has to be taken into account.
- Additional information: According to Article 3(4), flavourings may contain food additives as permitted by Regulation (EC) No 1333/2008 and/or other food ingredients incorporated for technological purposes.
- The Commission Services consider that when assessing the "95/5-ratio" of a "flavouring component", it is necessary to take into account the amount of "flavouring preparations" and "natural flavouring substances" from the labelled source compared to the total amount of flavouring component. According to the Commission Services, the entire flavouring preparation from the labelled source should be included for the purpose of this measurement.
- This interpretation has been confirmed by the competent EU Commission Services and the broad majority of the Members of the Standing Committee on the Food Chain and Animal Health (SCoFCAH). [Standing Committee on Food Chain and Animal Health, section Toxicology, 11 January 2013]
- Hence in the following examples (natural strawberry flavouring and natural lemon flavouring) – when assessing the 95/5-ratio of the flavouring component, it is necessary to take into account the entire flavouring preparation derived from the source materials (strawberry or lemon in our examples). This includes:
 - Constituents that are naturally present in a flavouring preparation due to their presence in the source material (e.g. water, intrinsically present in strawberries 90%)
 - Remaining amounts of 'foods or food ingredients' that were used as extraction solvents within the scope of Directive 2009/32 during the manufacturing process.

Composition of a strawberry

	Value g/100 g
Water	90
Fat	0,40
of which saturated	0,04
Carbohydrates	5,51
of which sugars	4,40
Polyols	0,06
Fibers	1,63
Protein	0,82



Other constituents	Value g/100 g
Acids, minerals and flavouring materials	1,58

Source: Souci, Fachmann & Kraut (2016), *Die Zusammensetzung der Lebensmittel Nährwert-Tabellen*, 8th Auflage

An illustrative example of a commercial « Natural strawberry flavouring » according to Art. 16 (4) (95/5-ratio)

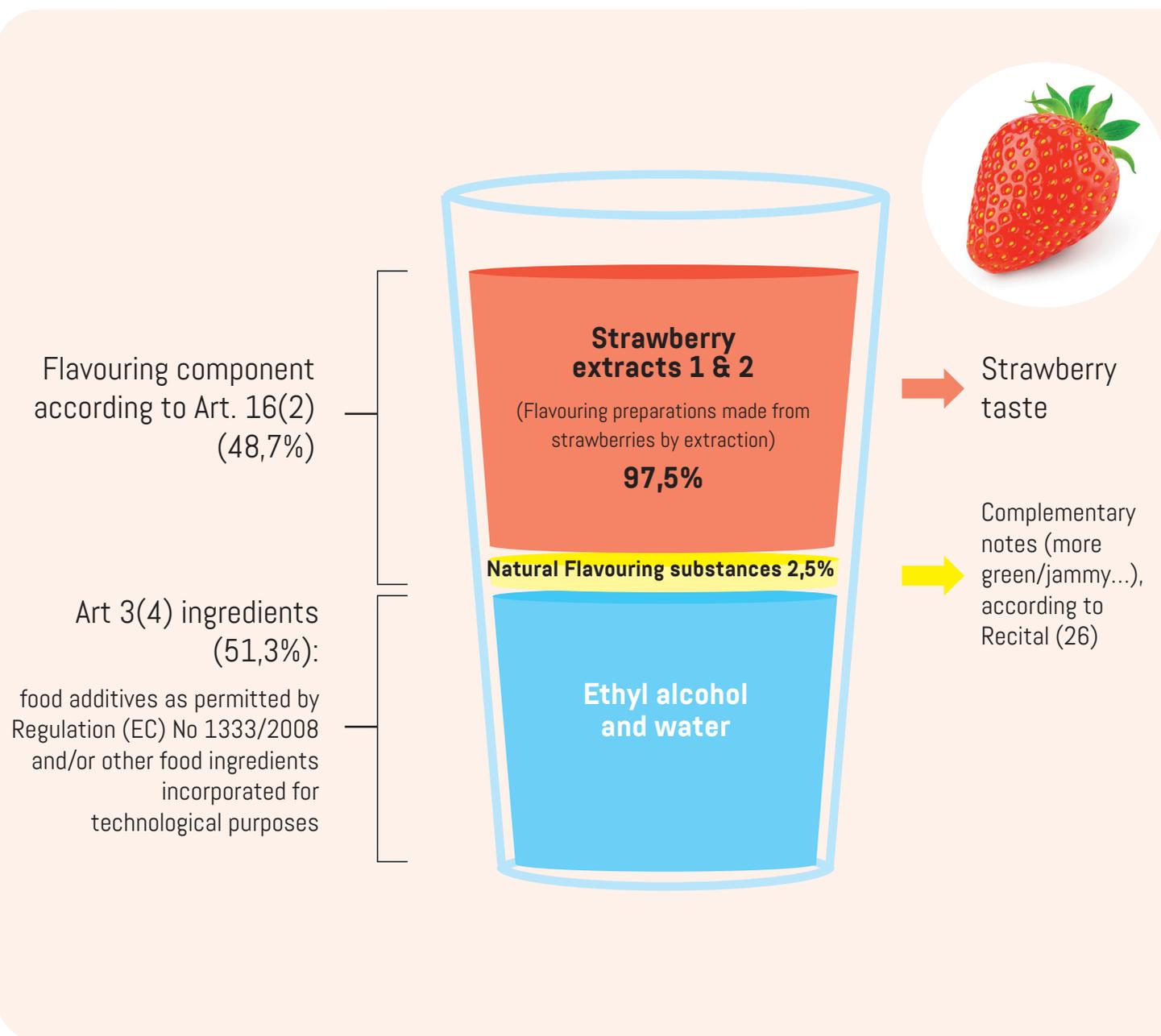
Part of the flavouring	Ingredients (Flavouring component and other ingredients)		Quantity / 100g flavouring	Quantity % of the flavouring component	
Flavouring component according to Art. 16(2)	Flavouring preparation	Strawberry extract n°1*	32,8g	67,3%	97,5% w/w of the flavouring component issued from the named source (strawberry)
	Flavouring preparation	Strawberry extract n°2*	14,7g	30,2%	
	Natural flavouring substances	ethyl butyrate furanol <i>cis</i> -3-hexenol	1,2g	2,5%	2,5% w/w of the flavouring component from substances not issued from the named source (strawberry)
Art. 3(4) ingredients	Solvents and/or carriers	Water/Ethanol	51,3g		

Total = 100g

Dosage of natural strawberry flavouring in the final food (depending on the matrix): 0,2-0,3%

* "extracts" = Flavouring preparations made from strawberries by extraction

Example of a Natural strawberry flavouring



An illustrative example of a commercial « Natural lemon flavouring » according to Art. 16(4) (95/5-ratio)

Part of the flavouring	Ingredients (Flavouring component and other ingredients)		Quantity / 100g flavouring	Quantity % of the flavouring component	
Flavouring component according to Art. 16(2)	Flavouring preparation	Lemon extract n°1*	40,0g	40,0%	97,6% w/w of the flavouring component issued from the named source (lemon)
	Flavouring preparation	Lemon extract n°2*	24,0g	24,0%	
	Flavouring preparation	Lemon extract n°3*	20,0g	20,0%	
	Flavouring preparation	Lemon extract n°4*	8,0g	8,0%	
	Flavouring preparation	Lemon extract n°5*	5,6g	5,6%	
	Flavouring preparation	Orange oil	0,1g	0,1%	2,4% w/w of the flavouring component from other preparations and substances not issued from the named source (lemon)
	Natural flavouring substances	Linalool Geranyl acetate Geraniol	2,3g	2,3%	
Art. 3(4) ingredients	Solvents and/or carriers	None	0g		

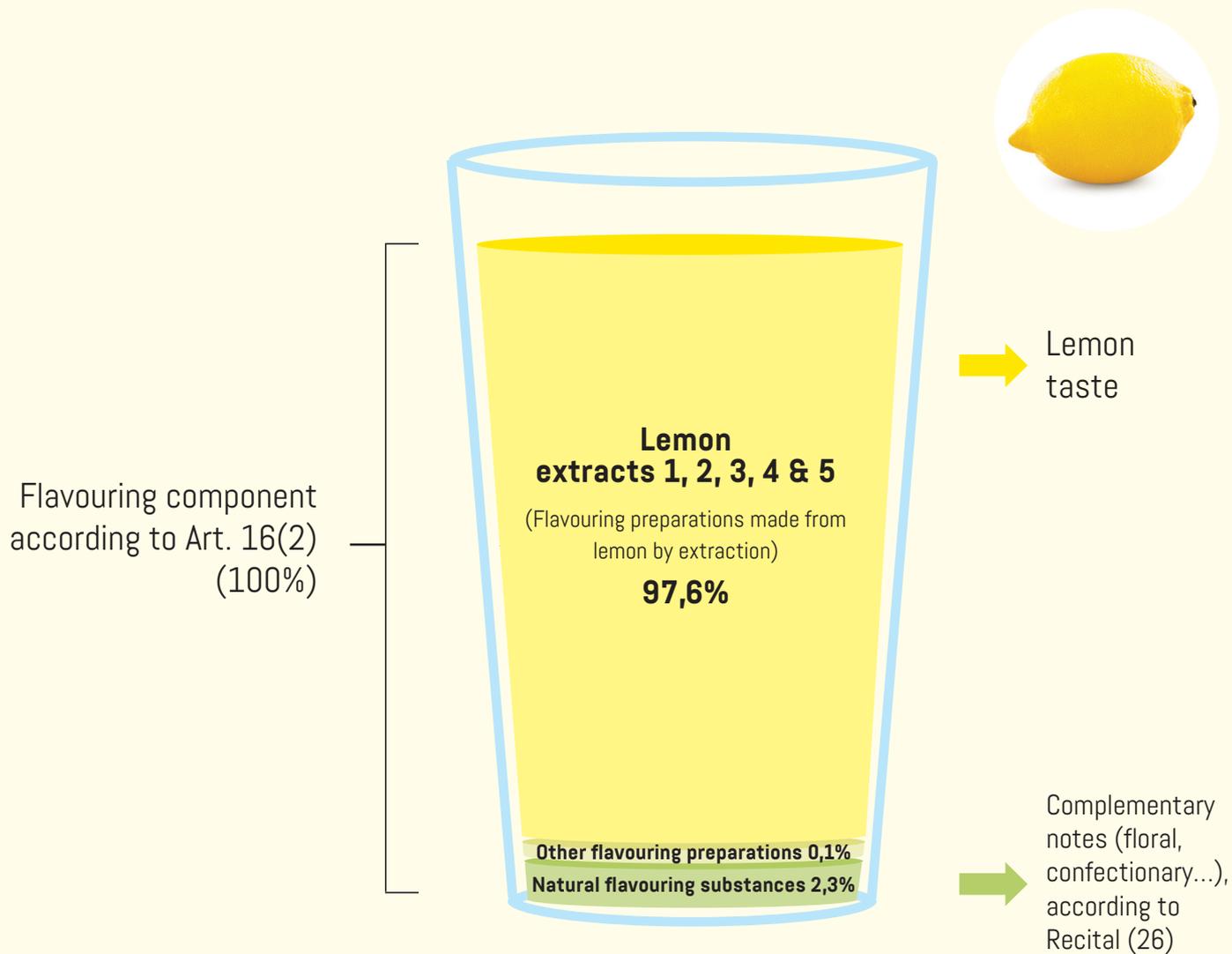
Total = 100g

Dosage of natural lemon flavouring in the final food (depending on the matrix): 0,03 - 0,3%

* "extracts" = Flavouring preparations made from lemon by extraction



Example of a Natural lemon flavouring



An illustrative example of a commercial « Natural lemon flavouring » according to Art. 16(4) (95/5-ratio)

Part of the flavouring	Ingredients (Flavouring component and other ingredients)		Quantity / 100g flavouring	Quantity % of the flavouring component	
Flavouring component according to Art. 16(2)	Flavouring preparation	Lemon extract n°1*	10,5g	95,5%	96,4% w/w of the flavouring component issued from the named source (lemon)
	Flavouring preparation	Lemon extract n°2*	0,1g	0,9%	
	Flavouring preparation	Lime extract	0,1g	0,9%	3,6% w/w of the flavouring component from other preparations and substances not issued from the named source (lemon)
	Flavouring preparation	Peppermint extract	0,1g	0,9%	
	Natural flavouring substance	Beta-pinene	0,2g	1,8%	
Art. 3(4) ingredients	Solvents and/or carriers	Ethanol, Propylene glycol	89g		
Total = 100g					

Dosage of natural lemon flavouring in the final food (depending on the matrix): 0,1 - 0,6%

* "extracts" = Flavouring preparations made from lemon by extraction



Example of a Natural lemon flavouring

