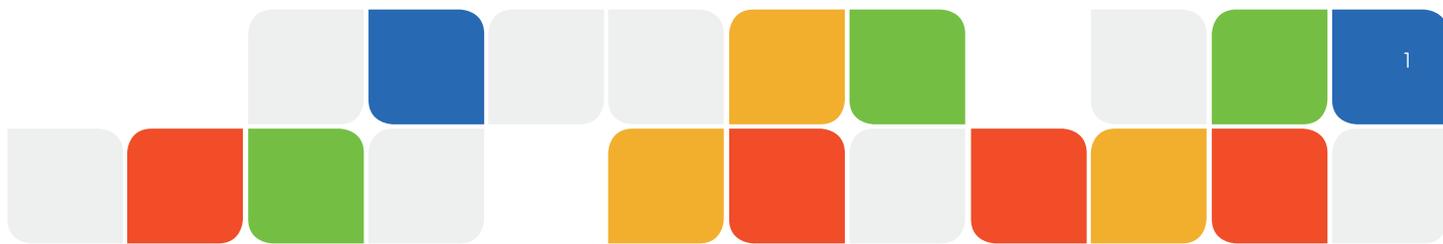




Guidelines on Flavourings

Table of Contents

EXECUTIVE SUMMARY	1
1 SCOPE AND DEFINITIONS	2
1.1 Scope: Article 2	2
1.2 Definitions: Article 3	2
a) Flavourings	2
b) Food Ingredients with flavouring properties	5
c) Source materials	5
1.3 Flavourings with Modifying Properties	6
2 TIMESCALE FOR IMPLEMENTATION OF THE UNION LIST	7
2.1 Timeline for the Implementing Regulation 872/2012 adopting the List of Flavouring Substances Part A of Annex I referred to in Regulation 1334/2008	7
2.2 Timeline for Regulation 873/2012 on transitional measures for Annex I Parts B-F of the Union List referred to in Regulation 1334/2008	8
3 SALES DESCRIPTION FOR FLAVOURINGS	9
3.1 General labelling	9
3.2 Provisions for the use of the term natural	9
3.2.1 Use of the term "natural": Art. 16 (2)	9
3.2.2 "Natural flavouring substance(s)": Art. 16 (3)	10
3.2.3 "Natural X flavouring": Art. 16 (4)	10
3.2.4 "Natural X flavouring with other natural flavourings": Art. 16 (5)	12
3.2.5 "Natural flavouring": Art. 16 (6)	13
4 LABELLING OF FLAVOURINGS IN THE INGREDIENTS LIST OF FLAVOURED FOOD AND BEVERAGES	14
4.1 Introduction	14
4.2 Examples how to use B2B information to determine possible designations in the B2C labelling	17
5 UNDESIRABLE SUBSTANCES LISTED IN ANNEX III ARTICLE 6	19
5.1 Substances which may not be added as such to foods	19
5.2 The "major contributors approach"	19
5.3 Special cases: Annex III B – note at bottom of page (*)	20
6 COMMUNICATION OF DATA AND MONITORING OF INTAKE	21
6.1 Information to be communicated by food business operators: Art. 19	21
6.2 Intake and reports from Member States: Art. 20	22
7 ORGANOLEPTIC CONTROLS	23
8 UNION LIST OF FLAVOURING SUBSTANCES AND SOURCES MATERIALS ANNEX I TO THE EU REGULATION 1334/2008	24
ANNEX I - EFFA GUIDANCE DOCUMENT ON FLAVOURINGS WITH MODIFYING PROPERTIES (FMP)	25
ANNEX II - TIMESCALE FOR THE APPLICATION OF REGULATION (EC) NO 1334/2008	25
II.1 Entry into force and date of application of the Regulation: Art. 30	25
II.2 End of marketing of non-complying foods and flavourings: Art. 30	26
a) Labelling compliance	26
b) Compositional flavouring compliance to Annexes III to V	26
II.3 Community list of flavourings and source materials: Arts. 8 to 13	26
II.4 Situation at Member State Level	27



Executive Summary

The present Industry Guidelines on the “Regulation (EC) No 1334/2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods” are intended to provide a common understanding of the major issues to be taken into account by food business operators, flavourings producers and other stakeholders.

The Guidelines are divided into different Chapters and Annexes. They include the original text as provided in the Regulation (in coloured text boxes), interpretations and industry’s common understanding as well as some illustrative examples to highlight specific cases. Several statements and positions follow consultation with the Commission Services and, where applicable and available, their interpretation is included.

Chapter 1, “Scope and definitions”, provides a brief overview on the scope and definitions provided in the Regulation, including some illustrative examples.

Chapter 2, “Timescale for implementation of the Union List”, consists of a summary diagram on the timescale for implementation, where additional information and national specific issues are provided in Annex I.

Chapter 3, “Sales description for flavourings”, including the use of the term “natural” and its possible designations are highlighted.

Chapter 4, “Labelling of flavourings in the ingredients list of flavoured food and beverages”, examines the possibilities for labelling flavourings in the ingredients list of flavoured products. Different cases and examples are included.

Undesirable substances as listed in the Regulation in Annex III Article 6 are provided in **Chapter 5**.

Chapter 6 and 7 are devoted to the communication of data and monitoring of intake and organoleptic controls, respectively.

Chapter 8 refers to the Union List of flavouring substances and sources materials in Annex I of the Regulation (EC) No 1334/2008.

Annex I: Guidance on the use of Flavourings with modifying properties.

Annex II: Timescale for the application of Regulation (EC) No 1334/2008.

Disclaimer:

These Guidelines were developed by FoodDrinkEurope members. They are intended to provide a common understanding on the major issues to be taken into account. The statements and interpretations provided in these Guidelines aim at reflecting a European-wide point of view and should not prejudice national interpretations. Ultimately, however, it is a matter for each company to determine the appropriate interpretation.

1 Scope and definitions

1.1 Scope: Article 2

The Regulation applies to:

- A Flavourings used or intended to be used in or on foods and to source materials for flavourings
- B Food ingredients with flavouring properties and to source materials for these ingredients
- C Foods containing flavourings and/or food ingredients with flavouring properties

The Regulation does not cover:

- A Substances which have an exclusively sweet, sour or salt taste, such as sugar, salt or citric acid
- B Raw foods
- C 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

1.2 Definitions: Article 3

a) Flavourings

Article 3 (2) (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.
- (ii) made or consisting of the following categories: flavouring substances, flavouring preparations, thermal process flavourings, smoke flavourings, flavour precursors or other flavourings or mixtures thereof.

Each of the categories described below is a “flavouring”. The term flavouring can apply to a product consisting of only one of these categories or a mixture of several of the categories and/or food additives and/or other food ingredients incorporated for technical purposes.

Flavouring substances

Article 3 (2) (b) – “Flavouring substance” shall mean a defined chemical substance with flavouring properties.

Example:

- Flavouring substance: menthol, ethyl butyrate

Natural flavouring substances

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.

Example:

- Natural flavouring substance: menthol obtained by fractionated distillation from mint oil. Limonene obtained by steam distillation from oranges

Flavouring preparations

Article 3 (2) (e) – “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.

Examples:

- A mint extract is a flavouring preparation, whereas menthol is a flavouring substance
- A vanilla extract is a flavouring preparation, whereas vanillin is a flavouring substance
- Orange oil or black pepper oleoresin are flavouring preparations

Thermal process flavourings

Article 3 (2) (d) “Thermal process flavouring” shall mean a product obtained after heat treatment from a mixture of ingredients not necessarily having flavouring properties themselves, of which at least one contains nitrogen (amino) and another is a reducing sugar; the ingredients for the production of thermal process flavourings may be:

- food; and/or
- source material other than food.

Smoke flavourings

Article 3 (2) (f) – “Smoke flavouring” shall mean a product obtained by fractionation and purification of a condensed smoke yielding primary smoke condensates, primary tar fractions and/or derived smoke flavourings as defined in points (1), (2) and (4) of Article 3 of Regulation (EC) No 2065/2003.

Flavour precursors

Article 3 (2) (g) – “flavour precursor” shall mean a product, not necessarily having flavouring properties itself, intentionally added to food for the sole purpose of producing flavour by breaking down or reacting with other components during food processing; it may be obtained from:

- (i) food; and/or
- (ii) source material other than food.



Examples of starting materials:

- Carbohydrates, oligopeptides and amino acids

Industry's understanding

The term “food processing” includes any action that substantially alters the initial products, and includes processes such heating, smoking, curing, maturing, drying, marinating, extraction, extrusion (and others) or a combination of such processes. “Food Processing” can be carried out by food business operators as well as by final consumers when preparing food for consumption.

Other flavourings

Article 3 (2) (h) – “Other flavouring” shall mean a flavouring added or intended to be added to food in order to impart odour and/or taste and which does not fall under definitions given in b) to g).

Example:

- Rum ether is a “complex Flavour mixture” falling under “Other flavourings” it is produced by reaction of different components and cannot be considered as a “Flavouring preparation”

b) Food Ingredients with flavouring properties

Article 3 (2) (i) – “Food ingredient with flavouring properties” shall mean a food ingredient other than flavourings which may be added to food for the main purpose of adding flavour to it or modifying its flavour and which contributes significantly to the presence in food of certain naturally occurring undesirable substances.

Example:

- Cinnamon (contains coumarin) in bakery wares

c) Source materials

Article 3 (2) (i) – “Source material” shall mean material of vegetable, animal, microbiological or mineral origin from which flavourings or food ingredients with flavouring properties are produced; it may be:

- (i) food; or
- (ii) source material other than food.

Examples:

- **Unprocessed** foods: Fruits, Vegetables, Mushrooms, Meat, Fish, Rose petals, Spices, Aromatic plants
- **Processed** foods: Black soya beans (fermentation/ torrefaction), Cheese (enzymatic action), Green coffee (torrefaction)

Industry’s understanding

According to Regulation 178/2002/EC¹, food is considered 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, 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 context². This is considered to take account of materials used anywhere worldwide³ for these purposes prior to the application date 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.

Annex IV of the Regulation provides a list of source materials to which restrictions of use apply:

- Part A lists source materials⁴ not to be used for the production of flavourings and/or food ingredients with flavouring properties
- Part B provides conditions of use for some other source materials⁵

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

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

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

4 Tetraploid form of *Acorus calamus* L.

5 *Quassia amara* L. and *Picrasma excelsa* (Sw), *Laricifomes officinales* (Vill.: Fr) Kott. et Pouz or *Fomes officinalis*, *Hypericum perforatum* L., *Teucrium chamaedrys* L.

1.3 Flavourings with Modifying Properties

The current definition specifies that a flavouring is a product that imparts or modifies odour and/or taste. The Commission published Guidance notes on the classification of a flavouring substance with modifying properties and a flavour enhancer⁶ which helps the notifier of the substance to classify its product as a flavouring or as an additive and consequently to gather the correct information for the evaluation which has to be carried out by EFSA.

The European Flavour Association (EFFA) produced a Guidance document on Flavourings with Modifying Properties (FMPs), which covers both the use of flavouring substances with modifying properties and flavouring preparations with modifying properties. The objective is to provide supplementary guidance to the flavouring industry and to the food industry on how to establish the appropriate use of flavourings with modifying properties. This document includes the following topics:

- Preliminary remarks
- Supplemental guiding elements
- Definitions and Terminology
- Determination of the functional effects
- Maximum advised use levels

and provides relevant information on how to perform sensory profiling. All the related documents are available in Annex I.

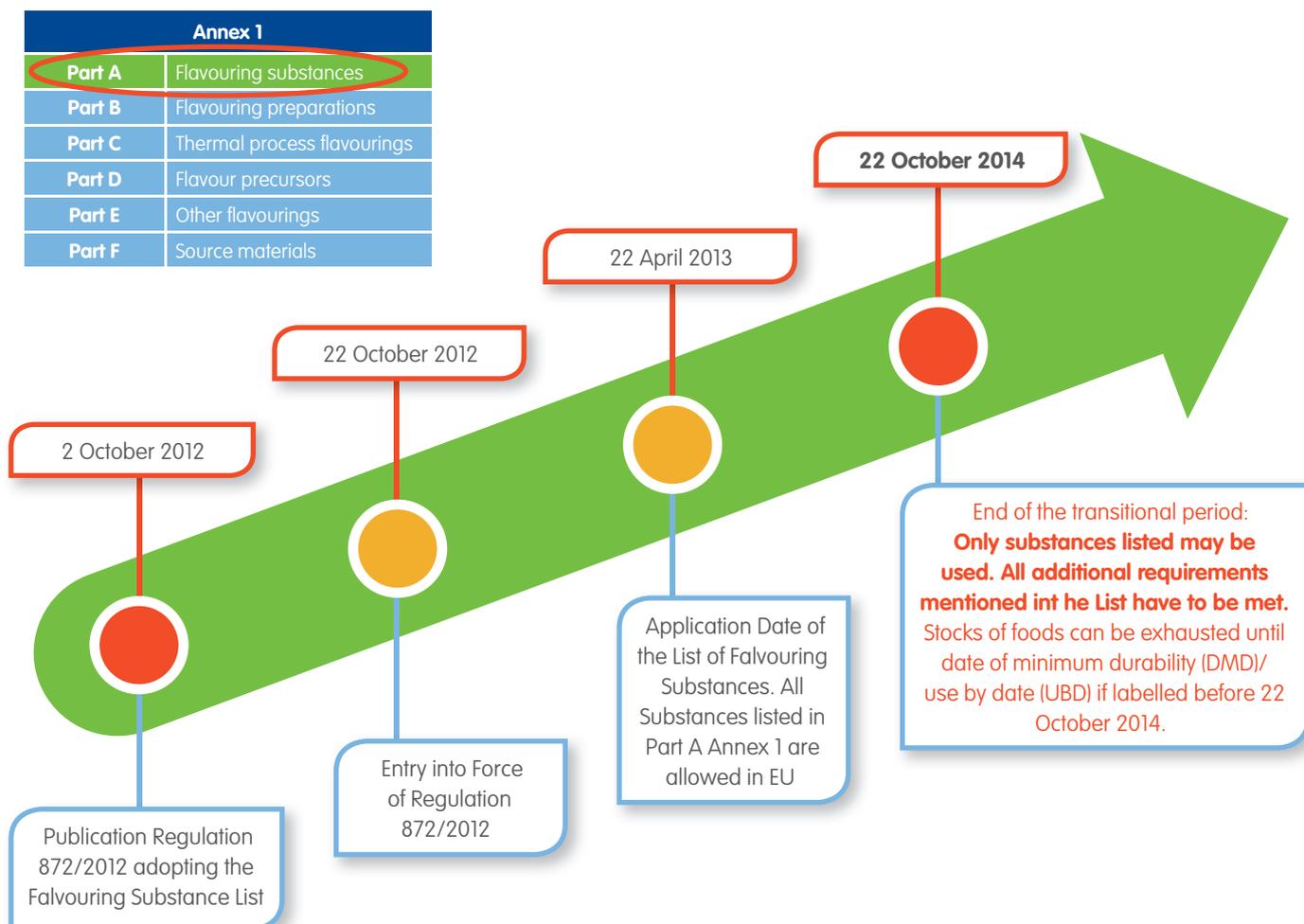
6 http://ec.europa.eu/food/food/fAEF/flavouring/guidance_notes_modifying_properties_en.htm.

2 Timescale for Implementation of the Union List

As a first step, a Union list of flavouring substances has been established by Commission Regulation (EU) No 872/2012 (2) by introducing the list of flavouring substances into Annex I to Regulation (EC) No 1334/2008 and by fixing the dates of application of that list.

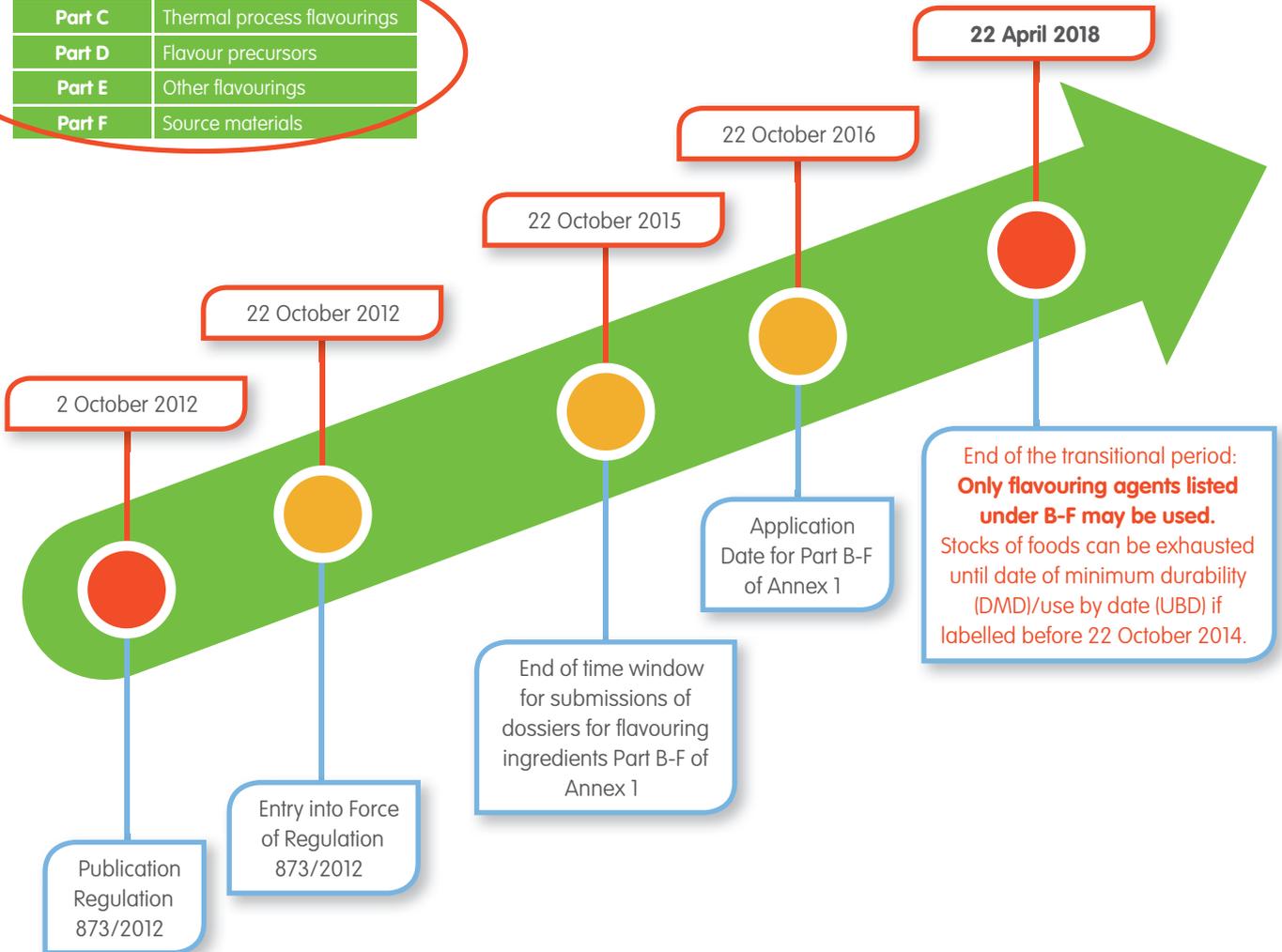
As a second step, the flavourings and source materials referred to in Article 9(b) to (f) must be evaluated. Commission Regulation (EU) No 873/2012 provides transitional measures for this achievement.

2.1 Timeline for the Implementing Regulation 872/2012 adopting the List of Flavouring Substances (Part A of Annex I referred to in Regulation 1334/2008)



2.2 Timeline for Regulation 873/2012 on transitional measures for Annex I Parts B-F of the Union List referred to in Regulation 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



3 Sales Description for Flavourings

3.1 General labelling

The general labelling requirements are laid down in Article 15. Art 15(1) (a) stipulates that the sales description of flavourings shall be either “flavouring” or a more specific name or description of the flavouring.

The reference to a source without the term natural (e.g. apple flavouring) is only seen as a description of the taste and not of the source material.

3.2 Provisions for the use of the term natural

Specific requirements for the use of the term “natural” are laid down in Article 16.

3.2.1 Use of the term “natural”: Art. 16 (2)

Article 16 Specific requirements for use of the term “natural”:

Paragraph 2: 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.

For all the examples detailed below, the use of the term “natural” to describe a flavouring is possible only if **the flavouring component is made up exclusively of natural flavouring preparations and/or natural flavouring substances**.

The inclusion of all other categories of flavourings (flavouring precursors, smoke flavourings, etc...) prevents the flavouring from being described as natural.

Additives and other ingredients present in a flavouring do not jeopardize its natural status, therefore food ingredients such as vegetable oil and maltodextrin and carriers such as propylene glycol do not alter the natural status.

Recital 26 indicates that “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”. In general, recitals may express the legislators’ intention and do therefore help in the interpretation of the Regulation, but they are not legally binding. Only Art 16(5) relating to “Natural X Flavouring WONF” (see below 3.2.3) specifically requires recognition of the flavour of “X” (for more information please consult Chapter 4).

3.2.2 “Natural flavouring substance(s)”: Art. 16 (3)

Article 16 Specific requirements for use of the term “natural”:

Paragraph 3: The term “natural flavouring substance(s)” may only be used for flavourings in which the flavouring component contains exclusively natural flavouring substances.

A flavouring in which the flavouring component is made up only of natural flavouring substances may be labelled “natural flavouring substances”.

Industry’s understanding

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

It is possible to supplement the wording “natural flavouring substance(s)” with information such as the name of the substance (e.g. menthol, vanillin) if this information may seem of interest to the consumer.

3.2.3 “Natural X flavouring”⁷: Art. 16 (4)

Article 16 Specific requirements for use of the term “natural”:

Paragraph 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 recognised.

Additional information on 95/5 rule

- Assessment of the 95/5-ratio

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) have to be obtained from the source material(s) referred to.

7 “X” stands for “food(s) or food category or source(s)”.

When considering a “flavouring preparation in the quantitative determination of 95/5”, the entire “flavouring preparation”⁸ has to be taken into account. Due to the way they are produced, flavouring preparations are complex mixtures not containing solely volatile flavouring molecules. Therefore the presence of constituents that are naturally present 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. Substances subsequently added as agents for diluting or dissolving such flavouring preparations are not considered as being part of them and are therefore subject to separate indication in B2B documents.

- Special requirements for the 5%

Recital (26) of the Regulation refers to the other maximum 5% of the flavouring component (from other sources). This text is interpreted as follows:

As the use of flavourings should not mislead the consumer concerning the source materials used for the production of natural flavourings, the remaining maximum 5% w/w from other sources should only be used to adjust natural variations in the flavour profile to ensure a consistent quality and/or to introduce special notes to the flavouring such as a more fresh, pungent, ripe or green note. 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). This can also be illustrated by the fact that adding 5% of natural vanillin not derived from vanilla beans to provide the vanilla taste of a “natural vanilla flavouring” is not allowed.

Additional information:

In cases where the origin of the flavour accounts for 100% from the source, other denominations may be used, e.g. “X extract” or “X essential oil”, as defined also by ISO Standard 9235:2013⁹.

What can X be: “food or food category or source material”?

X may be one or more “food(s)”

Industry’s understanding

It is possible to name several foods provided that the total of the named sources corresponds to at least 95% by weight.

FoodDrinkEurope recalls the general obligation not to mislead the consumer. Thus it is possible to cite one or more foods if the flavouring component provides at least 95% of the named foods and the other 5% are only used for standardisation or to give, for example, a more fresh, pungent, ripe or green note to the flavouring.

FoodDrinkEurope recommends mentioning the major contributor first (based on weight).

Non-exhaustive list of examples:

- “Natural raspberry flavouring”
- “Natural goat cheese flavouring”
- “Natural pear (and) apricot flavouring”

8 This has been adopted in the Standing Committee on Food Chain and Animal Health in 2013: interpretation of Article 16(4) of Regulation (EC) No 1334/2008 on flavourings – assessment of the 95/5 ratio:
http://ec.europa.eu/food/committees/regulatory/scfcah/toxic/docs/sum_31012013_flavourings_en.pdf.

9 http://www.iso.org/iso/home/store/catalogue_ics/catalogue_detail_ics.htm?csnumber=51017.

X may be a “food category”

Industry’s understanding

It is possible to make reference to food categories as commonly understood by the consumers and which is not misleading, always taking into account the locally applicable rules.

As an example in the French Syrup decree 92-812-2003, red fruits are defined as blueberry/cranberry, blackcurrant, strawberry, redcurrant, cherry, sweet cherry and acerola.

Non-exhaustive list of examples:

- “Natural citrus flavouring”
- “Natural herb flavouring”
- “Natural red berries flavouring”

3.2.4 “Natural X flavouring with other natural flavourings”: Art. 16 (5)

Article 16 Specific requirements for use of the term “natural”:

Paragraph 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.

The Regulation does not set minimum requirements on the proportion of X w/w but consumer must not be misled, Article 4(b).

Industry’s understanding

Recital 26

...When less than 95% of the flavouring component derived from the source referred to has been used and the flavour of the source can still be recognised, the source should be revealed together with a statement that other natural flavourings have been added...

To use the sales description “natural X flavouring with other natural flavourings” it is required that flavouring materials derived from the named source(s) are present and that their flavour can easily be recognised¹⁰.

¹⁰ It is recognised 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.

3.2.5 “Natural flavouring”: Art. 16 (6)

Article 16 Specific requirements for use of the term “natural”:

Paragraph 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.

There are two cumulative conditions:

1. The flavouring component is derived from different source materials

AND

2. Reference to the source materials does not reflect their flavour or taste

Industry's understanding

If **a single source material** is used and **its flavour is not recognisable**, it should be possible to label **“natural flavouring”**.

The term “natural flavouring” is available for flavourings when no clear relationship between the different source materials used in the flavouring component and the overall taste exists. In case of uncertainty about this relationship, it is recommended to use the term “natural flavouring”.

4 Labelling of flavourings in the ingredients list of flavoured food and beverages

4.1 Introduction

The requirements for the labelling of flavourings in the ingredients list are laid down in Part D of Annex VII Regulation (EU) No 1169/2011. Points 1 and 2 explicitly refer to the relevant provisions of Regulation (EC) 1334/2008. It is worth noticing that no reference to the recitals of Regulation (EC) 1334/2008 is made in Regulation (EU) 1169/2011.

The purpose of the recitals is to “set out concise reasons for the chief provisions of the enacting terms [i.e., legislative provisions]”¹¹. In other words, “recitals” are the part of an act which state the reasons on which the act is based.

In basic acts, such as a Regulation, recitals explain the general philosophy of the act rather than giving all the reasons for each specific provision laid down therein. However, specific reasons for a number of individual provisions can also be given in the recitals of a Regulation¹².

As recitals explain the background to a Regulation, as well as its aims and objectives, they are important to a correct understanding of the legislative provisions which follow. Indeed, their purpose is – among others – “to enable the Court of Justice of the European Union to exercise its power of review¹³”, and they are therefore relevant when interpreting a legislative text.

However, recitals do not contain normative provisions and they have no binding legal force.

Recitals of Regulation (EC) 1334/2008 state the reasons on which the Regulation is based and they are therefore relevant for understanding its provisions, including the ones which relate to the designation of flavourings in the list of ingredients.

In this regard, recital 7 makes it clear that the aim of the Regulation is to also cover the labelling of flavourings when present in the final food (“[...] the use of flavourings must not mislead the consumer and their presence in food should, therefore, always be indicated by appropriate labelling [...]”).

Recitals 25, 26 and 27 explain the reasons for the requirements applying to the use of the term “natural” in the designation of flavourings in the list of ingredients and they are therefore relevant when interpreting Article 16, which lays down the requirements applicable in this respect.

Recital 26, in particular, explains that the aim of the information requirements applying to the use of the term “natural” is to ensure that consumers are not misled concerning the source material used for the preparation of a natural flavouring. It also states the principle that the source of a natural flavouring should be indicated in labelling, except in specific cases.

11 Legal service, European Parliament et al., Joint Practical Guide of the European Parliament, The Council and the Commission for persons involved in the drafting of legislation within the Community Institutions (2013) [hereinafter Joint Practical Guide], available at <http://eurlex.europa.eu/content/pdf/techleg/joint-practical-guide-2013-en.pdf> p. 19.

12 Id., p. 21.

13 Id., p. 19.

Industry's understanding

The appropriate designation in the list of ingredients lays in the remit of the food operator of the final food. The decision must always be made on a case by case basis taking into account several aspects including amongst others:

- the nature and composition of the final food (see example 1)
- as mentioned in the EFFA Guidance, the labelling of the flavouring provided by the flavour industry (sales description) is a helpful indication. In case of uncertainty it is recommended to consult the flavour supplier for additional information or help
- the EU country where the product is lawfully placed in the market. Local national interpretations should be taken into account

The comments below are intended to illustrate industry's position.

1. A flavouring may be designated either by the term **"flavourings"** or by a more specific term or by a **description**, such as for example those defined in Article 3 (see 1.2 Definitions). Examples of more specific terms would be "mint oil" or "vanilla extract" as defined for example by ISO Standard 9235/2013¹⁴

Examples of a more specific description would be a reference to the taste: raspberry flavouring, lemon flavouring

Special provisions are laid down for smoke flavourings. These shall be labelled as "smoke flavourings" or "smoke flavouring(s) produced from "food(s) or food category source(s)" if they impart a smoky taste to the food

2. For labelling in the list of ingredients, the rules relating to the sales description of the flavourings (Art. 16) must be respected when using the word natural (see chapter 3 of these Guidelines). The legislation allows different labelling options. A few cases are considered below
3. When quinine and caffeine are used as flavouring substances (FL14.011 and FL 16.016, respectively) special provisions for labelling have to be followed

If the name of the flavouring contains the terms "tea" or "coffee", the reasonable consumer can presume that the flavouring contains caffeine. Therefore, the goal of Article 1 of Directive 2002/67/EC would be achieved and no additional indication concerning caffeine is necessary

Industry's understanding

If caffeine is inevitably present in minor amounts in flavourings (for example from decaffeinated coffee) this then should not trigger a specific mention of caffeine in the list of ingredients. The "carried over" quantities that are to be found in the food will be of such a small order of magnitude that they would not have a function in the end product. The labelling of flavouring in such cases would create consumer expectations which could not be fulfilled and would therefore mislead consumers.

Example 1: Natural vanilla flavouring used in chocolate

In this case a natural vanilla flavouring is used in chocolate. The chocolate does not taste significantly of vanilla, but the flavouring is used to round off the overall taste.

Article 18.4 and Annex VII, Part D, point 2 of Regulation 1169/2011 (FIC) lay down the specific provisions for the use of the term “natural” in order to designate flavourings in the list of ingredients.

Annex VII, Part D specifically refers to the Article 16 of Regulation (EC) 1334/2008 (flavour Regulation). This implies that all provisions of Article 16 need to be applied for the designation of natural flavourings in the list of ingredients. Article 16.4 of Regulation (EC) 1334/2008 sets the requirements for use of term natural and reads as follows: “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”. It does not mention that the source has to be recognised. We believe that therefore the name of the source should be indicated, even if the taste of the source material of the flavouring component cannot be recognised in the food. It is true that Recital 26 explains the spirit of the Regulation 1334/2008 and reads as following: “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”. We believe that this recital applies for the interpretation of the full Article 16 with all its paragraphs.

This means that for “natural X flavourings”, “natural X with other natural flavourings”, “natural flavourings”, the indication of the source are the same i.e. that the source should be labelled. The source should be labelled unless specific conditions are laid down. And these specific conditions are laid down only in the Articles 16.5 (natural flavouring with other natural flavourings) and 16.6 (natural flavourings) through the additional sentences.

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”.

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. 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.

When looking back at the genesis of the Regulation (EC) 1334/2008, it was clear that both Commission and Council were of the opinion that the indication of the source was of the utmost importance for the information of the consumer. The best example for this was that the amendment of the European Parliament to introduce possibility to designate “natural X flavouring” and “natural X flavourings with other natural flavourings” under the generic term “natural flavouring” was rejected.

Recommended labelling: “Natural vanilla flavouring”.

Example 2: Natural vanilla flavouring with other natural flavourings in a chocolate

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.

Taking into account Recital 26, we believe that Article 16.6 should be interpreted as referring to the flavour or taste of the flavouring in the food. In case the source cannot be recognised in the flavour or taste of the final food the designation “natural flavouring” is acceptable.

Recommended labelling:

- “natural vanilla flavouring with other natural flavourings” (the flavour is recognised in the final food)
- “natural flavouring ” (the flavour is not recognised in the final food)

4.2 Examples how to use B2B information to determine possible designations in the B2C labelling

The options listed in the examples below are included according to the interpretation provided in these Guidelines. They are intended to help the food business operators use the information received from the flavour supplier to determine the designation of the flavouring in the ingredient list of the final food. The concept can be used for other flavouring combinations.

B2B information	Possible B2C Designation
Natural orange and grapefruit flavouring	<p>Ingredients: (...), natural orange and grapefruit flavouring, (...)</p> <p>Ingredients: (...), natural citrus fruit flavouring, (...) Orange and grapefruit are citrus fruits = food category</p> <p>Ingredients: (...), natural citrus fruit (orange and grapefruit) flavouring, (...)</p> <p>Ingredients: (...), orange and grapefruit flavouring, (...)</p> <p>Ingredients: (...), citrus flavouring, (...)</p> <p>Ingredients: (...), flavouring, (...)</p>
Natural strawberry flavouring with other natural flavourings	<p>Ingredients: (...), natural strawberry flavouring with other natural flavourings, (...)</p> <p>Ingredients: (...), natural flavouring, (...) If not easily recognisable in the final food</p> <p>Ingredients: (...), strawberry flavouring, (...)</p> <p>Ingredients: (...), flavouring, (...)</p>

B2B information	Possible B2C Designation
Natural lemon flavouring and natural strawberry flavouring used together in a foodstuff	Ingredients: (...), natural strawberry flavouring, natural lemon flavouring (...) Ingredients: (...), natural strawberry and lemon flavourings, (...) Ingredients: (...), strawberry and lemon flavourings, (...) Ingredients: (...), flavourings, (...)
Natural lemon flavouring and natural strawberry flavouring with other natural flavourings used together in a foodstuff	Ingredients: (...), natural lemon flavouring, natural strawberry flavouring with other natural flavourings (...) Ingredients: (...), natural lemon and natural strawberry flavouring with other natural flavourings, (...) Ingredients: (...), natural lemon flavouring, natural flavouring, (...) If the strawberry flavourings is not easily recognisable in the final food Ingredients: (...), strawberry and lemon flavourings, (...) Ingredients: (...), flavourings, (...)
Natural lemon flavouring and vanilla flavouring used together in a foodstuff	Ingredients: (...), natural lemon flavouring, vanilla flavouring, (...) Ingredients: (...), lemon and vanilla flavourings, (...) Ingredients: (...), flavourings, (...)
Natural lemon flavouring, natural orange flavouring, and natural strawberry flavouring used in several foodstuffs sold together in one package (e.g. box of sweets with different tastes)	Ingredients: (...), natural lemon flavouring, natural orange flavouring, natural strawberry flavouring, (...) Ingredients: (...), natural lemon, orange, strawberry flavourings, (...) Ingredients: (...), natural fruit flavourings (lemon, orange strawberry), (...) Ingredients: (...), natural fruit flavourings, (...) Ingredients: (...), flavourings, (...)
Natural cheese flavouring in snack	Ingredients: (...), natural cheese flavouring, (...) Ingredients: (...), cheese flavouring (...) Ingredients: (...), flavouring, (...)
Bacon flavouring containing a primary smoke (SF 001)	The smoky taste is perceptible in the food: Ingredients: (...), bacon flavouring, smoke flavouring, (...) Ingredients: (...), flavouring, smoke flavouring, (...) Ingredients: (...), flavouring, smoke flavouring from beech and oak, (...) Ingredients: (...), bacon flavouring, smoke flavouring from beech and oak, (...) The smoky taste is not perceptible in the food: Ingredients: (...), flavouring, (...) Ingredients: (...), bacon flavouring, (...)

5 Undesirable substances listed in Annex III Article 6

5.1 Substances which may not be added as such to foods

Article 6 - Presence of certain substances

1. Substances listed in Part A of Annex III shall not be added as such to food.

Several substances are listed. They are substances found naturally in certain foodstuffs and shall not be added as such to foods.

5.2 The “major contributors approach”

Article 6 - Presence of certain substances

2. Without prejudice to Regulation (EC) No 110/2008, maximum levels of certain substances, naturally present in flavourings and/or food ingredients with flavouring properties, in the compound foods listed in Part B of Annex III shall not be exceeded as a result of the use of flavourings and/or food ingredients with flavouring properties in and on those foods. The maximum levels of the substances set out in Annex III 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.

Annex III part B sets “maximum levels for certain substances which are naturally present in flavourings or in food ingredients with flavouring properties which must not be exceeded in the specified foods incorporating flavourings or food ingredients with flavouring properties”. The food categories do not follow the Guidance document describing the food categories in Part E of Annex II to Regulation (EC) No 1333/2008 on Food Additives¹⁵, i.e. “non-alcoholic beverages” does not include herbal and fruit infusions or tea.

The levels apply under the following conditions:

- by substance
- by listed categories of food: the presence of these substances is only limited for the listed foods which have been identified as “major contributors”

Example: the presence of coumarin must not be higher than:

- ✓ 50mg/kg in traditional and/or seasonal bakery wares, containing a reference to cinnamon in the labelling
- ✓ 20mg/kg in breakfast cereals
- ✓ 15mg/kg in fine bakery wares except for traditional and/or seasonal bakery wares, containing a reference to cinnamon in the labelling
- ✓ 5mg/kg in desserts

In other food categories there are no limits for the presence of these substances but the provisions of the General Food Law apply.

15 http://ec.europa.eu/food/food/fAEF/additives/docs/guidance_1333-2008_descriptors_annex2_20131218_en.pdf.

5.3 Special cases: Annex III B – note at bottom of page (*)

Annex III Presence of certain substances – Part B – footnote (*)

(*) The maximum levels shall not apply where a compound food contains no added flavourings and the only food ingredients with flavouring properties which have been added are fresh, dried or frozen herbs and spices. After consultation with the Member States and the Authority, based on data made available by the Member States and on the newest scientific information, and taking into account the use of herbs and spices and natural flavouring preparations, the Commission, if appropriate, proposes amendments to this derogation.

There is an exception for three substances:

- Estragol
- Methyleugenol
- Safrol

For these substances, the maximum levels do not apply to compound foods within the scope of the Regulation:

- Which do not contain any flavourings¹⁶
AND
- Which contain food ingredients with flavouring properties which are uniquely fresh, dried or frozen herbs and spices

16 This has been clarified by the Commission and Member States to refer to flavourings which contain the active principle only. It is possible to use flavourings provided that they don't add to the level.

6 Communication of data and monitoring of intake

6.1 Information to be communicated by food business operators: Art. 19

Article 19 Reporting by the food business operators

1. A producer or user of a flavouring substance, or the representative of such producer or user, shall, at the request of the Commission, inform it of the amount of the substance added to foods in the Community in a period of 12 months. The information provided in this context shall be treated as confidential insofar as this information is not required for the safety assessment.

Information on the use levels for specific food categories in the Community shall be made available to Member States by the Commission.

(...)

When requested, there is an obligation for **producers and users of flavouring substances** to communicate to the Commission the quantity of a substance added to foods in the Community during the course of a 12 month period.

Industry's understanding

The responsibility to transmit information directly should affect the food industry **only for flavouring substances purchased directly and added to food directly, and not for those purchased which are part of formulated flavourings**. Once flavouring substances are used in the formulation of a flavouring, the responsibility to provide information to the Commission lays with the flavouring manufacturer.

Because flavouring manufacturers cannot be sure in what products their flavourings are used (these might be non-food applications and food exported from the EU) and because the flavouring manufacturers do not have information on the dosage levels used by the food operator, considerable overestimation of consumption is likely to occur.

Article 19 Reporting by the food business operators

(...)

4. Detailed rules for the implementation of paragraph 1 shall be adopted in accordance with the regulatory procedure referred to in Article 21(2).

Note: the method of transmission of information and the collection by the authorities will be determined by Comitology. This position may therefore be revised once the procedure is defined.

6.2 Intake and reports from Member States: Art. 20

The Member States must put in place a monitoring system according to Article 20.

Article 20 Monitoring and reporting by the Member States

1. Member States shall establish systems to monitor the consumption and use of flavourings set out in the Community list and the consumption of the substances listed in Annex III on a risk-based approach, and shall report their findings with appropriate frequency to the Commission and to the Authority.
2. After the Authority has been consulted, a common methodology for the gathering by Member States of information on the consumption and use of flavourings set out in the Community list and of the substances listed in Annex III shall be adopted in accordance with the regulatory procedure referred to in

Article 21(2) by 20 January 2011.

The monitoring and reporting by Member States includes:

- intake and use of flavourings in the Union list
- intake of substances included in Annex III

The substances in Annex III present in food as a result of:

- The use of food ingredients with flavouring properties
AND/OR
- The use of flavourings derived from certain source materials

Consequently, the manufacturers of foods containing flavourings and/or food ingredients with flavouring properties must be in a position to communicate equivalent data. At the date of publication of the guidance no common methodology to gather the necessary data has been published.

N.B: Flavouring manufacturers are seeking to make available to the authorities all the relevant information.

7 Organoleptic Controls

Organoleptic controls are carried out in a '2-step' approach.

- **Step 1** relates to the "sales description" of flavourings according to Articles 15.1(a) and 16 of the Regulation. The responsibility for the "sales description" remains with the supplier of the flavouring. For further guidance on step 1 and how to understand subjective elements such as "easy recognition", the EFTA Guidance Document on the EC Regulation on Flavourings¹⁷ should be consulted
- **Step 2** relates to the "Designation of flavourings in the list of ingredients" as outlined in Article 29. The manufacturer of the final food is responsible for the denomination on the final product

The controls should be carried out in a matrix depending on the product/solubility of the individual flavouring.

¹⁷ <http://www.ffa.eu/media/news/44/664/EFFAGDNewECFlavouringRegV302ndrev110313.pdf>.

8 Union List of flavouring substances and sources materials - Annex I to the EU Regulation 1334/2008

The List of flavouring substances has been adopted and published on 02/10/2012 by the Commission Implementing Regulation EU No 872/2012. The list forms part A Annex I of Regulation (EC) No 1334/2008.

What information is given in Annex I part A?

FL No.:	The unique identification number of the substance
Chemical Name:	The name of the substance
CAS No.:	The Chemical Abstracts Service (CAS) registry number
JECFA No.:	The Joint FAO/WHO Expert Committee on Food additives (JECFA) number
CoE No.:	The Council of Europe (CoE) number
Purity of the named substance at least 95% unless otherwise specified:	The purity of the named flavouring substance has to be at least 95%. If less, the composition of the flavouring substances is given in this column.
Restrictions of Use:	The use of flavouring substances is permitted in accordance with good manufacturing practices unless specific restriction is given in this column. Flavouring substances with restrictions of use may only be added to the listed food categories and under the specified conditions of use. For the purpose of the restrictions the food categories, as laid down in Annex II of Regulation (EC) No 1333/2008, shall be referred to.

FL No.	Chemical Name	CAS No.	JECFA No.	CoE No.	Purity of the named substance at least 95% unless otherwise specified	Restrictions of Use	Footnote	Reference
07.215	d-Camphor	464-49-3	1395	140		In category 1 – not more than 16 mg/kg In categories 2 and 8 – not more than 50 mg/kg In category 3 – not more than 20 mg/kg In categories 5, 6, 7, 12 and 15 – not more than 100 mg/kg In category 14.1 – not more than 50 mg/l In category 14.2 – not more than 50 mg/l (except not more than 850 mg/l in <i>Schwedenbitter</i>)		EFSA

The Commission published an electronic database based on the Union List which is available from the following website: https://webgate.ec.europa.eu/sanco_foods/main/?event=display

However, the only legal texts remain the Regulations as published.

Transitional measures for the application of this Union List are explained in Annex II timescale for application of this guideline.

ANNEX I - EFFA Guidance document on Flavourings with Modifying Properties (FMP)

The EFFA Guidance document is available online here (Attachment X):
<http://www.ffa.eu/en/publications/guidance-documents>

ANNEX II - Timescale for the application of Regulation (EC) No 1334/2008

II.1 Entry into force and date of application of the Regulation: Art. 30

Article 30 Entry into force

This Regulation shall enter into force on the 20th day following its publication in the Official Journal of the European Union.

It shall apply from 20 January 2011.

Article 10 shall apply from 18 months after the date of application of the Community list.

Articles 26 and 28 shall apply from the date of application of the Community list.

Article 22 shall apply from 20 January 2009.

(...)

The Regulation entered into force 20 days following publication:

⇒ Publication 31/12/2008 → entry into force 20/01/2009

Application was compulsory 24 months following entry into force:

⇒ Publication 31/12/2008 → entry into force 20/01/2009 → application 20/01/2011

In addition, Article 27 of Regulation (EC) No 1334/2008 states that the list of flavouring substances should have been adopted the latest by 31/12/2010. This list of flavouring substances has been adopted and published on 02/10/2012 by the Commission Implementing Regulation EU No 872/2012 (see chapter 8 Union List of flavouring substances and source materials: Annex I Part A).

II.2 End of marketing of non-complying foods and flavourings: Art. 30

Article 30 Entry into force

(...)

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

This timeline concerns foods already packaged and in stock, and not stocks of packaging.

a) Labelling compliance

As of 20/01/2011, the labelling of **flavourings** has to comply with Article 15¹⁸.

b) Compositional flavouring compliance to Annexes III to V

As of 20/01/2011, formulators of flavourings and of flavoured foods have to comply with the provisions laid down in:

- Annex III: presence of certain substances which may not be added as such to foods, and for which the presence in certain foods is limited
- Annex IV: short list of source materials, the use of which in the production of flavourings and food ingredients with flavouring properties is subject to restrictions
- Annex V: maximum levels of certain substances for thermal process flavourings

II.3 Community list of flavourings and source materials: Arts. 8 to 13

The Regulation requires certain flavourings and source materials to be evaluated and authorised. According to Article 10 a Community List of flavourings and source materials had to be established. This list is now called Union list as a consequence of the Lisbon Treaty.

The list of flavouring substances has been adopted and published on 02/10/2012 by the Commission Implementing Regulation EU No 872/2012 and introduced the Annex I of Regulation (EC) No 1334/2008 (see chapter 8 Union List of flavouring substances and source materials: Annex I Part A).

The list entered into force on 22/10/ 2012 and applied on 22/04/ 2013. As from that date, all substances included in the list could be used in or on foods.

Article 10 of the Regulation (EC) No 1334/2008 applies from 22/10/ 2014. This means that from this date on, only those substances listed in Part A of Annex I may be used in or on foods taking into account the conditions of use and specifications, where applicable.

¹⁸ General labelling requirements for flavourings not intended for sale to the final consumer.

The following flavourings and food ingredients with flavouring properties do not require evaluation (Article 8¹⁹):

- Flavouring preparations derived from foods
- Thermal process flavourings obtained from foods and manufactured in accordance to Annex V²⁰
- Flavour precursors obtained from food
- Food ingredients with flavouring properties

Article 9²¹ lists flavourings and source materials which require evaluation and authorisation:

- Flavouring substances
- Flavouring preparations derived from non-food sources
- Thermal process flavourings derived from of non-food sources and /or manufactured outside the conditions laid down in Annex V3
- Flavouring precursors derived from non-food sources
- Other flavourings
- Source materials other than food

These different categories of flavourings and source materials are mentioned as Part A to F of Annex I of Regulation (EC) No 1334/2008.

Parts B to F of the Union List will be populated later on after submission and evaluation and the application. The application date of those parts is foreseen as from the 22/10/2016.

Foods containing flavourings which are not included in parts A to E may still be placed on the market and used in or on food until 22/10/2016.

New flavourings and new source materials which were not legally placed on the market on the 22/10/2012 require the submission of a dossier according to the CAP.

Foods containing flavourings & source materials which are lawfully placed on the market or labelled prior to 22/04/2018 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.

II.4 Situation at Member State Level

National lists of authorised flavouring substances are repealed as of the date of application of the Union list 22/04/2013.

The Flavouring Regulation modified in the same way Regulation (EEC) No 1601/91 of 10 June 1991 on aromatised wines, and Regulation (EC) No 110/2008 of 15 January 2008, on spirit drinks²².

19 Flavourings and food ingredients with flavouring properties for which evaluation and approval are not required.

20 Annex V to EC/1334/2008 "Conditions for the production of thermal process flavourings and maximum levels for certain substances in thermal process flavourings".

21 Flavourings and source materials for which an evaluation and approval is required.

22 <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:039:0016:0054:EN:PDF>.

