



# Guidance on Flavourings

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## Summary

**Flavourings are substances or preparations added to food in order to improve or modify taste and/or odour, increasing its attractiveness for the consumer. Flavourings are not intended to be consumed as such. Rather, they are generally added to food in small amounts, sufficient to achieve the desired effect but resulting in relatively low exposure of consumers to the active flavouring principle(s).**

There are several thousand flavourings currently in use within the European Union (EU), many of these being found naturally in food (natural flavouring substances), and having a long history of safe use in a wide variety of foods. They fall into a number of categories, defined in the European legislation on flavourings, namely flavouring substances; natural flavouring substances; flavouring preparations; thermal process flavourings; smoke flavourings; flavour precursors; food ingredients with flavouring properties and other flavourings. In 1999, a Community Register of flavouring substances in use at that time was set up. The use of these substances in or on foodstuffs was permitted pending an evaluation of their safety and the establishment of a Union list (EU list) of authorised flavourings.

The currently applicable European legislation on flavourings and certain food ingredients with flavouring properties for use in and on foods, Regulation (EC) No<sup>1</sup> 1334/2008, became binding in Ireland in January 2011 and is part of the Food Improvement Agent Package (FIAP). FIAP provides a common EU authorisation procedure for all food flavourings (as well as food additives and food enzymes) via Regulation 1331/2008 and provides the basis for the Union list of authorised flavourings (the positive list), which was adopted on 1 October 2012 via Regulation 872/2012 and is applicable from 22 April, 2013. This legislation on flavourings replaces the previous Framework Directive 88/388/EEC and associated Directives and Decisions related to flavourings, together with the Community Register.

Flavourings or any food containing a flavouring and/or food ingredient with flavouring properties may not be placed on the market if their use does not comply with the requirements of Regulation 1334/2008. There is a general requirement that flavourings, source materials for flavourings and food ingredients with flavouring properties can only be used in or on foods if "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.

No maximum levels in food have been established for the majority of flavourings and food ingredients with flavouring properties. The use of flavourings in food is self-limiting, dependent on consumer preferences, and generally only small amounts are needed, sufficient to achieve the desired effect but resulting in relatively low exposure of consumers to the active flavouring principle. Maximum levels in food have however been established for the naturally-occurring substances 1,2-benzopyrone (coumarin), beta-asarone, 1-allyl-4-methoxybenzene (estragole), hydrocyanic acid, menthofuran, 4-allyl-1,2-dimethoxybenzene (methyleugenol), pulegone, quassin, 1-allyl-3,4-methylene dioxy benzene (safrole), teucriin A and thujone (alpha and beta). These flavouring substances and also the substances agaric acid, aloin, capsaicin and hypericine are considered to have adverse effects on health, including potential carcinogenicity, if consumed in excessive amounts, and the legislation stipulates that they should not be added directly as such to food. No maximum limits have been set for agaric acid, aloin, capsaicin and hypericine, as there was insufficient toxicological information to be able to do so. There is also a restriction on the use of certain source materials for the production of flavourings and food ingredients with flavouring properties. These are the "certain food ingredients with flavouring properties" alluded to in Regulation 1334/2008, and include quassia (source of quassin), white agaric mushroom (source of agaric acid), St John's wort (source of hypericine) and wall germander (source of teucriin A).

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<sup>1</sup> Hereafter in this guidance all EC Regulations are referred to as Regulation 1334/2008 rather than using the convention Regulation (EC) No 1334/2008

A core principle of Regulation 1334/2008 is that flavouring substances (those listed on the Community Register) and food ingredients with flavouring properties should be evaluated and approved at a European level before they can be used in food. The process for flavouring substances involves an assessment of their possible risks to health by the European Food Safety Authority (EFSA) or (in former years) by the EU Scientific Committee on Food (SCF), followed by addition of the flavouring substance to the Union list of authorised flavourings, which has recently been adopted. In the future, any new flavourings and source materials to be added to the list will be evaluated and approved according to the procedures established in Regulation 1331/2008.

Smoke flavourings are regulated under a stand-alone Regulation, Regulation 2065/2003. The safety assessment of these products has been ongoing since 2005, with the objective of producing a positive list of smoke flavourings that can be used to flavour food in the EU, together with the maximum levels of use and the food categories in which they may be used. Finalisation of this list is anticipated in 2012.

The presence of flavourings in food must be indicated by appropriate labelling. The use of flavourings and food ingredients with flavouring properties is subject to the general labelling provisions for food as established by Directive 2000/13/EC<sup>2</sup> relating to the labelling, presentation and advertising of foodstuffs, as amended. Regulation 1334/2008 introduces specific requirements in relation to the use of the term “natural” in the labelling of food flavourings. There are also more specific labelling requirements laid down in Regulation 1334/2008 for smoke flavourings and flavourings not intended for sale to the final consumer, i.e. for flavourings traded between one business and another. Also, where relevant, flavourings must comply with Regulation 1829/2003 and Regulation 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food products produced from genetically modified organisms.

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<sup>2</sup> Directive 2000/13/EC has now been replaced by Regulation 1169/2011, which came into effect on 13 December 2011. It will apply from 13 December 2014, with the exception of point (l) of Article 9(1) (mandatory nutrition declaration), which shall apply from 13 December 2016, and Part B of Annex VI (specific requirements regarding the designation of minced meat), which will apply from 1 January 2014.

## Chapter 1. Introduction

This guidance is aimed at the food industry and at food law enforcement officers. It seeks to clarify issues surrounding flavourings for use in food, including the legislation by which they are regulated and the labelling rules related to food to which flavourings have been added. The guidance replaces *Guidance Note No. 9 on Flavourings Legislation in Ireland (FSAI, 2002)* and covers only the legislation on flavourings used in food. Separate guidance has been published by the FSAI on food additives (FSAI, 2011).

Flavourings are used to improve or modify the taste and/or odour of foods in order to increase their appeal to the consumer. They can be grouped under specific headings, defined by the European Union (EU) legislation on flavourings, as follows:

- Flavouring substances
- Natural flavouring substances
- Flavouring preparations
- Thermal process flavourings
- Smoke flavourings
- Flavour precursors
- Food ingredients with flavouring properties
- Other flavourings

Flavourings are not intended to be consumed as such. Rather, they are generally added to food in small amounts, sufficient to achieve the desired effect but resulting in relatively low exposure of consumers to the active flavouring principle(s). There are several thousand flavourings currently in use within the EU. Many of these are found naturally in food (natural flavouring substances), and have a long history of safe use in a wide variety of foods. Changes in food consumption patterns and advances in food processing technology have however led to substantial innovation in the use of flavourings in food in recent years.

In parallel, new legislative requirements have been introduced for flavourings in recent years, as part of the Food Improvement Agent Package (FIAP). FIAP provides a common EU authorisation procedure for food flavourings, as well as food additives and food enzymes via Regulation 1331/2008, together with three individual Regulations on flavourings and certain food ingredients with flavouring properties for use in and on foods (Regulation 1334/2008), food additives (Regulation 1333/2008) and on food enzymes (Regulation 1332/2008). As outlined in more detail in Chapter 2, the new legislation on flavourings replaces and revokes the existing EC legislation, namely Directive 88/388/EEC, Decision 88/389/EEC and Directive 91/71/EEC. However, Regulation 2232/96, laying down a Community procedure for regulation of flavouring substances used or intended for use in or on foodstuffs, will only be repealed when the list of flavouring substances to be established under that Regulation (the positive list) is fully applicable (see Section 2.5.5. of this guidance).

## Chapter 2. Legislation on Flavourings

### 2.1. European Union General Legislation on Flavourings

New EU legislative requirements have been introduced for flavourings in recent years, as part of FIAP. Regulation 1334/2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods was adopted in 2008, together with the other Regulations constituting the FIAP, and entered into force on 20th January 2009. A two year transition period was allowed for the application of its provisions, and the requirements of the legislation were thus binding on Member States, including Ireland, from 20th January, 2011. The only exceptions to this date of application were (a) provisions related to amendment of the Annexes of the Regulation (Article 22), which applied from 20th January, 2009, and (b) certain provisions conditional on the date of application of the Union list of flavouring substances in 2013.

Regulation 1331/2008, together with the implementing Regulation 234/2011, is the other key component of FIAP applicable to flavourings and certain food ingredients with flavouring properties. Regulation 1331/2008 provides a common procedure for the assessment and authorisation of food flavourings, food additives and food enzymes. It also provides the basis for the Union lists of approved flavourings, food additives and food enzymes and a mechanism for updating these lists. Regulation 234/2011 lays down specific detail on the content, drafting and presentation of an application for inclusion of a new food improvement agent on the relevant Union list, the checking of the validity of applications and the type of information that should be included in the opinion of EFSA. In relation to flavourings, Regulation 234/2011 lays down specific data that are required for the risk assessment and risk management of flavourings, which are outlined in more detail in Chapter 3 of this guidance. Table 2.1 summarises the currently applicable Union legislation on flavourings and certain food ingredients with flavouring properties. An overview of this legislation is also provided on the FSAI website<sup>3</sup>.

**Table 2.1. Currently applicable (as of 01.01.2012) Union legislation on flavourings and certain food ingredients with flavouring properties and on the common authorisation procedure**

Legislative Instrument	Content of the Legislation
Regulation 1331/2008 <a href="http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:354:0001:0006:EN:PDF">http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:354:0001:0006:EN:PDF</a>	This Regulation establishes a common procedure for the authorisation (by the European Commission) for food additives, food enzymes and food flavourings, before they can be used in food.
Regulation 1334/2008 <a href="http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:354:0034:0050:EN:PDF">http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:354:0034:0050:EN:PDF</a>	This Regulation lays down the legislative requirements for flavourings and certain food ingredients with flavouring properties for use in and on foods.
Regulation 234/2011 <a href="http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:064:0015:0024:EN:PDF">http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:064:0015:0024:EN:PDF</a>	This Regulation lays down the specific data that are required for the risk assessment and risk management of food additives, food enzymes and flavourings.
Regulation 872/2012 <a href="http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:267:0001:0161:EN:PDF">http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:267:0001:0161:EN:PDF</a>	This Regulation adopts the list of flavouring substances provided for by Regulation 2232/96, introducing it into Annex I to Regulation 1334/2008. It repeals Regulation 1565/2000 and Decision 1999/217/EC (below).
Regulation 873/2012 <a href="http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:267:0162:0164:EN:PDF">http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:267:0162:0164:EN:PDF</a>	This Regulation provides transitional measures concerning the Union list of flavourings and source materials set out in Annex I of Regulation 1334/2008.
Commission Decision 1999/217/EC <a href="http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1999:084:0001:0137:EN:PDF">http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1999:084:0001:0137:EN:PDF</a>	This Decision gave force to a Community Register of flavouring substances that could be used in or on foodstuffs until the date of application of the list of chemically defined flavouring substances on 22 April 2013. The Decision is repealed as of that date.
Regulation 1565/2000 <a href="http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2000:180:0008:0016:EN:PDF">http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2000:180:0008:0016:EN:PDF</a>	This Regulation laid down a programme for the toxicological evaluation of the flavouring substances contained in the Register established under Commission Decision 1999/217/EC.

<sup>3</sup> [http://www.fsai.ie/lesigation/food\\_legislation/flavourings/introduction.html](http://www.fsai.ie/lesigation/food_legislation/flavourings/introduction.html)

Legislative Instrument	Content of the Legislation
Regulation 2065/2003 on smoke flavourings <a href="http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:309:0001:0008:EN:PDF">http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:309:0001:0008:EN:PDF</a>	Regulation 2065/2003 lays down the procedure for regulation and evaluation of the “primary products” which are the main ingredients in smoke flavourings, while the associated Regulation 627/2006 lays down quality criteria for analytical methods for sampling, identification and characterisation of these products.
Regulation 627/2006 <a href="http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:109:0003:0006:EN:PDF">http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:109:0003:0006:EN:PDF</a>	

In the case of flavourings and certain food ingredients with flavouring properties, the applicability of the procedures under Regulation 1331/2008 is complicated by the fact that at the date of application of Regulation 1334/2008, a harmonised list of approved flavourings had not been agreed at EU level, as was the situation with food additives. For this reason, Regulation 2232/96, which lays down a procedure for the adoption of a list of chemically defined flavouring substances (the Union list of authorised flavourings), is still part of the Union legislation of flavourings. It will remain in force until such time as a number of substances for which the EU risk assessment had not been completed at the time of entry into force of Regulation 872/2012 have been fully evaluated and they have been added to the Union list (see Section 2.5.5 of this guidance). At that time, the authorisation procedure for flavourings under Regulation 1331/2008 will be fully applicable.

The European Commission and Member States initially adopted a register of approximately 2,800 flavouring substances currently in use in food in the EU (Commission Decision 1999/217/EC, as amended<sup>4</sup>), based on information from industry and Member States. This register formed the basis of the Union list of authorised flavourings, and a programme for the toxicological evaluation of these substances, initially by the SCF and now by EFSA, was agreed via Commission Regulation 1565/2000. Deadlines for submission by industry of the necessary information for evaluation were set via Regulation 622/2002. The timescale for this evaluation programme and adoption of the positive list was initially five years, to be completed by the end of 2005, but substantial delays have occurred, and adoption of the positive list via Regulation 872/2012 was not achieved until October 2012.

Additionally, the use of flavourings and food ingredients with flavouring properties is subject to the general labelling provisions for food<sup>5</sup> as established by Council Directive 2000/13/EC<sup>6</sup> on the approximation of laws of the Member States relating to the labelling, presentation and advertising of foodstuffs, as amended, as well as to the more specific labelling requirements laid down in Regulation 1334/2008.

<sup>4</sup> Commission Decision 1999/217/EC has been amended seven times, by Commission Decisions 2000/489/EC, 2002/113/EC, 2004/357/EC, 2005/389/EC, 2006/352/EC, 2008/478 and 2009/163/EC, to reflect corrections to the entries or deletion of entries because of concerns regarding safety/failure of industry to provide data. For accurate information on the content of the Register, the listed Decisions should be checked individually.

<sup>5</sup> More information on the general labelling provisions for food can be found on the FSAI website, at: [http://www.fsai.ie/legislation/food\\_legislation/labelling\\_of\\_food.html](http://www.fsai.ie/legislation/food_legislation/labelling_of_food.html)

<sup>6</sup> Directive 2000/13/EC has now been replaced by Regulation 1169/2011, which came into effect on the 13th December 2011. It will apply from 13 December 2014, with the exception of point (l) of Article 9(1) (mandatory nutrition declaration), which shall apply from 13 December 2016, and Part B of Annex VI (specific requirements regarding the designation of minced meat), which will apply from 1 January 2014.

## 2.2 European Union Legislation on Smoke Flavourings

Smoke flavourings are one of the categories of flavourings specifically defined in Regulation 1334/2008 (see definition in section 2.5.2 of this guidance), and are subject to separate Union legislation which applies in addition to the general requirements of Regulation 1334/2008. Regulation 2065/2003 on smoke flavourings lays down the procedure for regulation and evaluation of the “primary products” which are the main ingredients in smoke flavourings, while the associated Regulation 627/2006 lays down quality criteria for analytical methods for sampling, identification and characterisation of these products. Further information on the evaluation of smoke flavourings in food is provided in Chapter 3 of this guidance.

## 2.3 Previous European Union Legislation on Flavourings

Prior to the adoption of FIAP, flavourings were regulated at Community level under Council Directive 88/388/EEC. This Directive provided rules on the use and labelling of flavourings and laid down technical specifications for flavourings. This Directive was subsequently amended by Directive 91/171/EEC to provide more specific rules on the labelling of flavourings in food. An associated Commission Decision, 88/379/EC, established an inventory of source materials and substances used in the preparation of flavourings which was the forerunner to the register of flavouring substances established in 1999 via Commission Decision 1999/217/EC. All three of these measures were repealed on 20th January 2011, the date of application of Regulation 1334/2008.

The core principles and provisions of the previous legislation on flavourings are maintained in Regulation 1334/2008, but new aspects include the possibility to adopt and update the Union list of authorised flavourings through the comitology with scrutiny procedure<sup>7</sup> laid down in Council Decision 2006/512/EC, following a proposal from the Commission to the Standing Committee on the Food Chain and Animal Health (SCOFCAH). The new legislation also provides for a core role for EFSA in the risk assessment of food flavourings.

## 2.4 National Legislation on Flavourings

The Union legislation on flavourings is implemented in national legislation by the European Communities (Flavourings for use in foodstuffs for human consumption) Regulations, 1992 (S.I. No 22 of 1992). It should be noted that these Regulations transpose the previous EU legislation described in section 2.3 above, which was repealed by Regulation 1334/2008. The Department of Health will, in due course, introduce national regulations to introduce measures to implement Regulation 1334/2008 and related legislation.

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<sup>7</sup> The scrutiny procedure refers to the process by which the European Parliament may oppose legislative proposals from the Commission that would normally be adopted by the comitology procedure (voted on by representatives of Member States). This procedure was introduced by Article 5a of [Council Decision 2006/512/EC](#) of July 17th 2006 “the European Parliament, acting by a majority of its component members, or the Council, acting by a qualified majority, may oppose the adoption of the said draft by the Commission, justifying their opposition by indicating that the draft measures proposed by the Commission exceed the implementing powers provided for in the basic instrument or that the draft is not compatible with the aim or the content of the basic instrument or does not respect the principles of subsidiarity or proportionality”

## 2.5 General Provisions of the Legislation

Regulation 1334/2008 lays down general requirements for safe use of flavourings in food and makes specific provisions related to:

- i. The general subject matter and scope of the legislation (Articles 1 and 2)
- ii. Definitions for different types of flavourings used in food (Article 3)
- iii. General conditions for use of flavourings or food ingredients with flavouring properties (Article 4)
- iv. Prohibition of non-compliant flavourings and/or non-compliant food (Article 5)
- v. Restrictions on certain flavouring substances and source materials (Articles 6 and 7)
- vi. Flavourings and food ingredients with flavouring properties for which evaluation and approval are not required (Article 8) and flavourings and source materials for which an evaluation and approval is required (Article 9)
- vii. The Union list of flavourings and source materials (Articles 10, 11 and 25)
- viii. Flavourings or source materials falling within the scope of Regulation 1829/2003 on on genetically modified food and feed (Article 12)

It also lays down detailed requirements for the labelling of food containing flavourings (Articles 14-18) as described in Chapter 4 of this guidance. Procedural, reporting and implementing provisions for food business operators and for Member States are contained in Articles 19 and 20, while remaining Articles deal with amendments to other Union legislation, repeals, etc.

### 2.5.1 Aim and scope of the legislation

The aim of the legislation (Article 1) is to ensure the effective functioning of the internal market by providing a system for regulation of flavourings and food ingredients with flavouring properties which is harmonised throughout the European Union. The legislation also aims to ensure a high level of human health and consumer protection, the protection of consumer interests, fair practices in food trade and the protection of the environment. The legislation applies (Article 2) to:

- (i) Flavourings used or intended to be used in or on foods (without prejudice to more specific provisions laid down in Regulation 2065/2003 on smoke flavourings),
- (ii) Food ingredients with flavouring properties,
- (iii) Food containing flavourings and/or food ingredients with flavouring properties and
- (iv) Source materials for flavourings and/or source materials for food ingredients with flavouring properties.

The terms “flavourings”, “food ingredients with flavouring properties” and “source material” are defined in the Regulation and reproduced below.

#### *Flavourings falling outside the scope of the legislation*

Substances that have exclusively a sweet, sour or salty taste, such as common salt or sugar, raw food which has not undergone any processing treatment (even if it imparts a flavour) and non-compound foods and mixtures such as fresh, dried or frozen spices and/or herbs, mixtures of tea and other products used as infusions fall outside the scope of the legislation, as long as they are consumed as such and/or have not been used as food ingredients. In relation to the reference to non-compound foods in this text, a compound food is one composed of several/many ingredients. Spices, herbs, teas etc. can be classified as non-compound, e.g. single, foods in their own right, and are consumed as such, although they are also used as ingredients in compound foods. In the former case, their use falls outside the scope of the Regulation, but in the latter they should be regarded as flavourings, subject to the requirements of the Regulation. Table 2.2 provides some examples of flavourings and flavouring materials that fall outside the scope of the legislation and others that require evaluation by EFSA before they can be used.

**Table 2.2 Examples of flavourings/flavouring materials that fall outside the scope of the legislation and others that require evaluation by EFSA before they can be used**

<b>Materials falling outside the scope of Regulation 1334/2001 or which may be within scope but do not require evaluation as flavourings</b>	<b>Require evaluation as flavourings</b>
Sugar	Chemically-defined flavouring substances
Salt	Oleoresins
Citric acid	Extracts produced by processing plant, animal, microbiological materials
Raw, unprocessed food that may have a flavour	Source material that has no history of consumption as food (unless it can be demonstrated to have been previously used as a source of flavourings)
Tea, mixtures of teas	
Other plant material used as infusions, e.g. camomile, mint, strawberry leaves	
Fresh, frozen, dried spices and herbs	
Source material that has a history of consumption as food	

Materials of vegetable, animal or microbiological origin which can be demonstrated to have previously 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 or as food as such. They do not need to be evaluated for their safety as flavourings (Recital 16 of Regulation 1334/2008).

### 2.5.2 Definitions of flavourings and food ingredients with flavouring properties

As already indicated in the introduction to this guidance, flavourings and food ingredients with flavouring properties can be grouped under specific headings or types, defined by the EU legislation on flavourings.

“**Flavourings**” are defined generally in Article 3(2)(a) of Regulation 1334/2008 as products that are:

- (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”

Article 3(2)) identifies the different types of flavouring products used in food, and these are further defined in Article 3 as follows:

- (b) **‘Flavouring substance’** means a defined chemical substance with flavouring properties
- (c) **‘Natural flavouring substance’** means 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
- (d) **‘Flavouring preparation’** means a product, other than a flavouring substance, obtained from:
  - (i) 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

- (ii) 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

Flavouring preparations produced from food do not need to undergo an evaluation or an approval procedure for use in and on foods unless there is doubt about their safety. However, the Regulation requires that the safety of flavouring preparations produced from non-food material, i.e. from anything that does not meet the definition of food under food law, should be evaluated and approved.

(e) **‘Thermal process flavouring’** means 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:

(i) Food

and/or

(ii) Source material other than food

As with flavouring preparations, thermal process flavourings preparations produced from food under specified conditions do not need to undergo an evaluation or an approval procedure for use in or on foods unless there is doubt about their safety. However, the Regulation requires that the safety of thermal process flavourings preparations produced from non-food material or not complying with certain conditions of production should be evaluated and approved (Recital 17 of Regulation 1334/2008).

(f) **‘Smoke flavouring’** means 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 2065/2003.

(g) **‘Flavour precursor’** means 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

Flavour precursors produced from food do not need to undergo an evaluation or an approval procedure for use in and on foods unless there is doubt about their safety. However, the Regulation requires that the safety of flavour precursors produced from non-food material should be evaluated and approved (Recital 19 of Regulation 1334/2008).

(h) **‘Other flavouring’** means 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 (b) to (g) above.

(i) **‘Food ingredient with flavouring properties’** means a food ingredient other than a flavouring 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.

Article 3 also defines the source material from which flavourings of the various types may be produced, as follows:

(j) **‘Source material’** means 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

Source material of vegetable, animal, microbiological or mineral origin other than food may only be authorised for the production of flavourings after its safety has been evaluated scientifically by EFSA (Recital 21 of Regulation 1334/2008). Following such an evaluation it is possible that use of only certain parts of the material may be authorised or conditions of use may be laid down. Source material that has a history of consumption as food, does not need to be evaluated.

The term “appropriate physical process” as used in a number of the definitions provided above is also defined in Article 3 of Regulation 1334/2008, as follows:

- (k) **‘Appropriate physical process’** means 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 ultraviolet (UV) radiation.

The definitions in Regulation 1334/2008 are broadly similar to those in the previous legislation on flavourings (Directive 88/388/EEC), although “process flavouring” has been replaced by “thermal process flavouring”, and the definitions of ‘natural flavouring substance’, ‘flavour precursor’, ‘food ingredient with flavouring properties’, ‘other flavouring’ and ‘source material’ have been newly introduced in Regulation 1334/2008.

Examples of each category are provided in Table 2.3.

**Table 2.3 Examples of the different categories of flavourings**

Category of Flavouring	Example
Flavouring substance	Amyl acetate made by chemical synthesis or found naturally in, e.g. bananas, apples, melon, etc
Natural flavouring substance	Amyl acetate obtained from bananas or limonene obtained from oranges
Flavouring preparation	Peppermint oil, other essential oils, extracts of plant material, etc.
Thermal process flavouring	A meat flavour made by heating xylose (a reducing sugar) and cysteine (an amino acid), flavours produced as a result of the Maillard reaction, etc
Smoke flavouring	A flavouring produced from smoke, generally smoke from burning wood. The smoke is then condensed to produce a liquid flavouring “primary product”
Flavour precursor	E.g. an unheated blend of amino acids and sugars which will produce a flavour in the final food when the latter is heated. Flavour precursors may be single substances or a mixture of substances
Other flavouring	Anything which does not fit into one of the above categories, e.g. flavourings which are obtained by heating oil or fat to an extremely high temperature for a very short period of time, resulting in a grill-like flavour
Food ingredient with flavouring properties	White agaric mushroom (contains agaric acid) and tarragon (contains estragole and methyleugenol)
Source material	Oranges, other fruits, vegetables, meat – anything from which a flavouring might be extracted/prepared

### What is the difference between a flavouring substance and a flavouring preparation?

Vanilla flavour is a good example to illustrate the difference between a flavouring substance and a flavouring preparation. *Vanillin* is the flavouring substance, which can be obtained by extraction from a natural source such as vanilla beans (natural flavouring substance) or made by chemical synthesis. *Vanillin* is a constituent in the flavour which by itself contributes a large part, close to 100%, of the total flavour impression. *Vanilla* is the extract from dried/fermented vanilla pods (also known as vanilla beans) and is the flavouring preparation. Vanilla extract has a high percentage of vanillin, but also other components which contribute to the overall flavour of vanilla. Over 250 components contribute to the flavour profile of vanilla.



### *Distinction between the definition of “natural flavouring substance” and “flavouring substance”*

An important distinction between Directive 88/388/EEC and Regulation 1334/2008 has been the introduction in the latter of “natural flavouring substance” as distinct from “flavouring substance”. In the previous legislation, the definition of flavouring substance encompassed substances obtained by a physical process from source material of animal or vegetable origin, regarded as natural flavouring substances, and also substances obtained by chemical synthesis or obtained by a chemical process. The latter were further divided into two groups:

- (a) Substances chemically identical to substances naturally present in source material of animal or vegetable origin (nature-identical substances)
- (b) Substances not chemically identical to substances naturally present in such source material

Controversy regarding the use of the word “natural” to describe substances in group (a) and the possibility that it would mislead consumers led to the changes introduced in Regulation 1334/2008, and to strict rules regarding the use of “natural” in the labelling of flavoured foodstuffs, as further outlined in Chapter 4 of this guidance.

### *Use of food additives and other ingredients in flavourings*

In addition to the components of a flavouring that give rise to its characteristic flavouring properties, e.g. a single flavouring substance or, in the case of a complex flavouring such as a smoke flavouring, a number of different substances, flavourings may contain food additives as permitted by Regulation 1333/2008 and/or other food ingredients incorporated for technological purposes (Article 3(4) of Regulation 1334/2008). For example, propylene glycol may be needed as a carrier for flavourings, dimethylpolysiloxane may be used as an antifoaming agent while benzoates may be included as preservatives. The additives that can be used in flavourings and other food improvement agents such as additives, enzymes and nutrients are laid down in Annex III of Regulation 1333/2008, which has recently been introduced via Regulation 1130/2011.

## **2.5.3 General conditions of use of flavourings and food ingredients with flavouring properties in food**

Flavourings as such or any food containing a flavouring and/or food ingredient with flavouring properties may not be placed on the market if their use does not comply with the requirements of Regulation 1334/2008. However, unlike the situation with food additives under Regulation 1333/2008, where conditions of use for each authorised additive are laid down in the Annexes of the Regulation, including maximum permitted levels of use and the specific categories of food in which the additive may be used, no specific conditions of use are laid down for flavourings, with certain exceptions as detailed below. There is a general requirement (Article 4) that flavourings and food ingredients with flavouring properties can only be used in or on foods if “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. Misleading the consumer includes, but is not limited to, issues related to the nature, freshness, quality of ingredients used, the naturalness of a product or of the production process, or the nutritional quality of the product, including its fruit and vegetable content.

### *Maximum levels for flavourings in food*

No maximum levels in food have been established for the majority of flavourings and food ingredients with flavouring properties, nor will maximum levels be applied for most flavourings in the future, although exceptions include d-camphor, caffeine, theobromine, neohesperidin dihydrochalcone, ammonium chloride and rebaudiside A, all of which have maximum levels assigned in the new EU list. There is also generally no restriction on the food categories in which flavourings can be used, provided they meet the general criteria of safety and non-deception of the consumer. Exceptions to this include quinine salts, which can only be used in non-alcoholic and alcoholic beverages, and flavourings and food ingredients with flavouring properties produced from quassia and agaric mushrooms, which may only be used in the production of bakery wares and alcoholic beverages respectively. It should be recognised that the use of flavourings in food is self-limiting, dependent on consumer preferences, and that generally only small amounts are needed, sufficient to achieve the desired effect but resulting in relatively low exposure of consumers to the flavouring itself. The position regarding use of flavourings and source materials in infant formulae, follow-on formulae, processed cereal-based foods and baby foods and dietary foods for special medical purposes intended for infants and young children falling within the scope of

Directive 2009/39/EC<sup>8</sup> (the PARNUTS Directive) is not fully harmonised within the EU and will be reviewed as part of the recast of that Directive. Currently flavourings can be used in these foods, dependent on national legislation in individual Member States. It should be noted however, that flavourings are generally used at lower concentrations in foods for infants and young children compared with general foods for the wider population.

Maximum levels have however been established (Article 6) for “*certain substances, naturally present in flavourings and/or food ingredients with flavouring properties*” in a number of foodstuffs, as listed in Annex III Part B of Regulation 1334/2008. The restricted substances include agaric acid, aloin, capsaicin, 1,2-benzopyrone (coumarin), hypericine, beta-asarone, 1-allyl-4-methoxybenzene (estragole), hydrocyanic acid, menthofuran, 4-allyl-1,2-dimethoxybenzene (methyleugenol), pulegone, quassin, 1-allyl-3,4-methylene dioxy benzene (safrole), teucrin A and thujone (alpha and beta), as shown in Table 2.4.

**Table 2.4 Maximum levels for certain flavouring substances in specified compound foodstuffs**

Name of the substance	Compound food in which the presence of the substance is restricted	Maximum level mg/kg or mg/l
Beta-asarone	Alcoholic beverages	1.0
1-Allyl-4-methoxybenzene, Estragol (*)	Dairy products	50
	Processed fruits, vegetables (incl. mushrooms, fungi, roots, tubers, pulses and legumes), nuts and seeds	50
	Fish products	50
	Non-alcoholic beverages	10
Hydrocyanic acid	Nougat, marzipan or its substitutes or similar products	50
	Canned stone fruits	5
	Alcoholic beverages	35
Menthofuran	Mint/peppermint containing confectionery, except micro breath freshening confectionery	500
	Micro breath freshening confectionery	3,000
	Chewing gum	1,000
	Mint/peppermint containing alcoholic beverages	200
4-Allyl-1,2-dimethoxybenzene, Methyleugenol (*)	Dairy products	20
	Meat preparations and meat products, including poultry and game	15
	Fish preparations and fish products	10
	Soups and sauces	60
	Ready-to-eat savouries	20
Pulegone	Non-alcoholic beverages	1
	Mint/peppermint containing confectionery, except micro breath freshening confectionery	250
	Micro breath freshening confectionery	2,000
	Chewing gum	350
	Mint/peppermint containing non-alcoholic beverages	20
Quassin	Mint/peppermint containing alcoholic beverages	100
	Non-alcoholic beverages	0.5
	Bakery wares	1
	Alcoholic beverages	1.5

<sup>8</sup> Directive 2009/39/EC of the European Parliament and of the Council of 6 May 2009 on foodstuffs intended for particular nutritional uses. OJ L 124, 20.5.2009, p. 21

Name of the substance	Compound food in which the presence of the substance is restricted	Maximum level mg/kg or mg/l
1-Allyl-3,4-methylene dioxy benzene, safrole (*)	Meat preparations and meat products, including poultry and game	15
	Fish preparations and fish products	15
	Soups and sauces	25
	Non-alcoholic beverages	1
Teucrin A	Bitter-tasting spirit drinks or bitter (1)	5
	Liqueurs (2) with a bitter taste	5
	Other alcoholic beverages	2
Thujone (alpha and beta)	Alcoholic beverages, except those produced from Artemisia species	10
	Alcoholic beverages produced from Artemisia species	35
	Non-alcoholic beverages produced from Artemisia species	0.5
Coumarin	Traditional and/or seasonal bakery ware containing a reference to cinnamon in the labelling	50
	Breakfast cereals including muesli	20
	Fine bakery ware, with the exception of traditional and/or seasonal bakery ware containing a reference to cinnamon in the labelling	15
	Desserts	5

(\*) 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.

(1) As defined in Annex II, paragraph 30 of Regulation 110/2008

(2) As defined in Annex II, paragraph 32 of Regulation 110/2008

All of these substances are recognised to have adverse effects on health including potential carcinogenicity if consumed in excessive amounts, and Table 2.4 (reproducing Annex III of Regulation 1334/2008) provides maximum levels for most of these undesirable substances, known as biologically active principles (BAPs), in a range of compound foodstuffs which contribute most to the dietary intake of the substance. These maximum levels take into account the need to protect human health while recognising their unavoidable presence in traditional foods. The legislation also specifies that these substances should not be added as such to food, but may only be present in food, up to the maximum level specified (in Table 2.4), as a result of the use of flavourings and/or food ingredients with flavouring properties in and on those foods. The substances are however permitted at any level in foods not included in Table 2.4 (Annex III Part B of the Regulation), unless there is doubt about the safety of such foods, provided, again, that they are not added directly to the food but are only present as a result of the use of flavourings and/or food ingredients with flavouring properties in the food. Food business operators are obliged to take into account the presence of these substances when using food ingredients with flavouring properties and/or flavourings for preparation of all food, in order to ensure that food which is not safe is not placed on the market (Recital 10 of Regulation 1334/2008).

The maximum levels are intended to apply to foods as marketed, except in the case of dried and/or concentrated foods which need to be reconstituted before use. In the latter case, the maximum levels laid down apply to the food reconstituted according to the instructions on the label, taking into account the minimum dilution factor.

Maximum levels have not been established for the substances agaric acid, aloin, capsaicin, or hypericine, that are also categorised as undesirable substances, as there were insufficient safety data to be able to do so. For capsaicin (the predominant flavour in chilli peppers) it was agreed by the MS that due to its pungency, its use is self limiting, so no maximum levels in food were required.

### **Restrictions on the use of certain source materials for the production of flavourings and food ingredients with flavouring properties**

There is also a restriction on the use of certain source materials for the production of flavourings and food ingredients with flavouring properties (Article 7). These are the “certain food ingredients with flavouring properties” referred to in the title of Regulation 1334/2008, which are the source of the substances referred to above. The tetraploid form of the plant *Acorus calamus* L. (Sweet Flag), which is a source of the carcinogen beta-asarone must not be used as a source material, and quassia (source of quassin), white agaric mushroom (source of agaric acid), St John’s wort (source of hypericine) and wall germander (source of teucriin A) may only be used for the production of flavourings and food ingredients with flavouring properties used in beverages and bakery wares (quassin) or in alcoholic beverages (white agaric mushroom, St John’s wort or wall germander).

Maximum levels of use and specific use categories will also be established for smoke flavourings on the EU market. These flavourings are regulated under a stand-alone Regulation, Regulation 2065/2003, as described in more detail in section 2.2 of this guidance above.

### **2.5.4 Evaluation and approval of flavourings and food ingredients with flavouring properties**

As with other food improvement agents such as food additives, a core principle of Regulation 1334/2008 (Article 9) is that flavourings and food ingredients with flavouring properties should be evaluated and approved at a European level before they can be used in food. This process involves an assessment of their possible risks to health by EFSA or (in former years) by the SCF, followed by addition of the flavouring to the Union list of authorised flavourings, as described in more detail in section 2.5.5. Given the very large number of flavourings and food ingredients with flavouring properties known to be used in food production internationally, the systematic evaluation of their safety has been a relatively slow process compared with that for other food additives. As already indicated, at the date of application of Regulation 1334/2008, a harmonised list of approved flavourings had not been agreed at Union level, as was the situation with food additives, and this work is still ongoing.

All food flavouring substances, flavouring preparations, thermal process flavourings, smoke flavourings, flavour precursors, other flavourings and source materials as defined in Article 3 should be evaluated and approved before use. There are however, certain exemptions from this requirement, as laid down in Article 8 and outlined as follows:

- Food flavouring preparations that have been “*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 of the Regulation*”, as defined in Article 3(2)(d)(i)
- Thermal process flavourings as defined in Article 3(2)(e), which have been produced from food (Article 3(2)(e)(i)) and which comply with the conditions for the production of thermal process flavourings and maximum levels for certain substances in thermal process flavourings set out in Annex V of the Regulation
- Flavour precursors which have been produced from food (Article 3(2)(g)(i))
- Food ingredients with flavouring properties

All of these may be used in or on foods without an evaluation and approval provided they do not pose a safety risk to the health of the consumer and their use does not mislead the consumer. Table 2.5 provides a list of traditional food preparation processes which can be used in the production of food flavouring preparations “*obtained from food by appropriate physical processes*” without triggering the need for an evaluation by EFSA.

**Table 2.5 Traditional food preparation processes used in the production of food flavouring preparations that do not trigger a requirement for evaluation of the preparation**

Chopping	Microbiological processes	Emulsification
Drying	Pressing	Filtration
Evaporation	Roasting/grilling	Maceration
Fermentation	Steeping	Mixing
Grinding	Coating	Percolation
Infusion	Cooling	Refrigeration/freezing
Heating, cooking, baking, frying (up to 240°C at atmospheric pressure) and pressure cooking (up to 120°C)	Distillation/rectification	Squeezing

The focus of the evaluation and approval procedure is therefore on flavouring substances (including natural flavouring substances) and flavouring preparations produced from flavouring substances or from a source other than food, together with thermal process flavourings, flavour precursors and source materials produced from a source other than food. Smoke flavourings are also subject to an evaluation and approval process, under Regulation 2065/2003.

### 2.5.5 Union list of flavourings and source materials

Regulation 1334/2008 provides the basis for a Union<sup>9</sup> list of flavourings and source materials approved for use in and on foods, as Annex I of the Regulation. The Union list will ultimately provide a list of flavourings and source materials that have been evaluated and approved according to the procedures established in Regulations 1334/2008, 234/2011, and prior to the enactment of these Regulations, according to the procedure laid down in Regulation 2232/96. Only these flavourings and source materials may be placed on the market as such and/or used in or on foods, taking into consideration any conditions of use specified in the list.

As already indicated in Section 2.1 of this guidance, at the date of application of Regulation 1334/2008 a harmonised list of approved flavourings and source materials had not been agreed at Union level. Regulation 872/2012 now provides a Union list of flavouring substances, with a date of application of 22 April 2013. This list constitutes Annex 1, Part A of Regulation 1334/2008. The list includes, however, a number of substances for which the EU risk assessment had not been completed at the time of entry into force of the Regulation. These substances are denoted in the list by a footnote (1), indicating that “evaluation [is] to be completed by the Authority”. Further footnotes (2), (3) and (4) indicate the deadlines for submission of additional data on these substances by industry, the latest of which is 31 December 2013. EFSA will continue its evaluation of these substances on an ongoing basis as the data required become available, and depending on the outcome of the evaluation either the footnote (1) will be removed or the substance itself will be deleted from the list because the requisite data have not been provided. This process should be complete, at the latest, by the end of 2014.

<sup>9</sup> The Regulation refers to the “Community list”; however this correctly should be termed the “Union list” following the terminology agreed under the Treaty of Lisbon.

### *Addition of new flavouring substances to the Union list*

The register of approximately 2,800 flavouring substances in use in food in the EU (Commission Decision 1999/217/EC, as amended) has formed the basis of the current Union list, and the toxicological evaluation of these flavouring substances has been based on the procedure laid down in Regulation 2232/96. Industry has periodically submitted applications for new flavouring substances to be added to the register/harmonised list, and these have been evaluated by EFSA on an ongoing basis in accordance with Regulation 2232/96. Regulation 234/2011 laid down more specific data requirements for the risk assessment and risk management of flavourings, taking into account the latest guidance from EFSA on data requirements, published in May, 2010<sup>10</sup>. These requirements of Regulation 234/2011 applied as of 11th September, 2011, and after that time, any new flavouring substances and source materials to be added to the Union list will be evaluated and approved according to the procedures established in Regulations 1331/2008 and 1334/2008, as amended by Regulation 234/2011.

### *Transitional measures concerning the Union list of flavourings and source materials*

The Union list adopted via Regulation 872/2012 contains flavouring substances only, constituting Annex 1, Part A of Regulation 1334/2008.

Foods containing flavouring substances which do not comply with Part A of Annex I to Regulation (EC) No 1334/2008 may be marketed until their date of minimum durability or use-by-date. No flavourings and source materials as referred to in Article 9 (b) to (f) of Regulation 1334/2008 (namely flavouring preparations, thermal process flavourings, flavour precursors, other flavourings and source materials other than food) have been evaluated by EFSA or SCF, other than the “certain food ingredients with flavouring properties” mentioned in section 2.5.3. In theory, in accordance with Article 10 of Regulation 1334/2008, these flavourings and source materials should no longer be used in and on foods at a time 18 months after the date of application of the Union list (22 April, 2014), since they are not included in the Union list. Also, there may be flavouring substances in use in the EU that were not included in the register.

Regulation 872/2012 thus establishes, in addition to Part A, the harmonised list of flavouring substances, Parts B, C, D, E and F, which will deal in the future with flavouring preparations, thermal process flavourings, flavour precursors, other flavourings and source materials respectively. In parallel with the adoption of Regulation 872/2012, a further Regulation 873/2012 has been adopted, that provides transitional measures allowing time for evaluation and authorisation of these materials.

Regulation 873/2012 specifies that flavouring substances not included in the Union list may be placed on the market as such and used in or on food until 18 months after the date of application of the Union list. The date of application of Parts B to F of Annex I to Regulation (EC) No 1334/2008, concerning flavourings and source materials listed in Article 9(b) to (f) of that Regulation, has been postponed until 22 October 2016, in order to allow time for evaluation and authorisation of these materials. In turn, industry has until 22 October 2015 to submit applications for authorisation of such materials, with a further period foreseen for EFSA to carry out the requisite evaluations and for the Commission to prepare proposals for addition of the various materials to Parts B, C, D, E and F of Annex 1 of Regulation 1334/2004.

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<sup>10</sup> EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids; Draft Guidance on the data required for the risk assessment of flavourings. *EFSA Journal* 2010; 8(6):1623 <http://www.efsa.europa.eu/en/scdocs/doc/1623.pdf>

Table 2.6 provides an overview of the various dates of application of the provision of Regulation 1334/2008 regarding flavouring substances, flavourings and source materials.

**Table 2.6 Overview of the various dates of application of the provisions of Regulation 1334/2008 regarding flavouring substances, flavourings and source materials**

Date	Applicable provision
22 April, 2013	Union list of flavouring substances (Part A of Annex 1 of Regulation 1334/2008) applies
December, 2013	Latest date for submission of data requested by EFSA on "footnote (1)" flavouring substances
22 October, 2014	Food containing flavouring substances not included in the Union list may be only be marketed after this date until such time as their date of minimum durability or 'use-by' date is reached
22 October, 2015	Deadline for submission of application by industry for authorisation of a flavouring preparation, thermal process flavouring, flavour precursor, other flavouring or source material
22 October, 2016	Parts B to F of Annex 1 of Regulation 1334/2008 apply.
22 October, 2016	Foods containing flavourings and source materials which do not comply with parts B to F of Annex 1 to Regulation 1334/2008 may be only be marketed after this date until such time as their date of minimum durability or 'use-by' date is reached

### 2.5.6 Flavourings or source materials falling within the scope of Regulation 1829/2003 on genetically modified food and feed

A flavouring or source material which falls within the scope of Regulation 1829/2003 on genetically modified food and feed should be authorised in accordance with that Regulation as well as under Regulation 1334/2008. This means that if the flavouring is produced by a process which may result in the presence of residues of genetic material from a genetically modified organism (GMO) or a genetically modified micro-organism (GMM) in the flavouring or if the source material is a GMO or GMM, it must first go through the safety evaluation and authorisation system for GMOs/GMMs before going through the evaluation and approval system for flavourings and source materials. However, under article 12 (2), when a flavouring already included in the Union list is produced from a different source material falling within the scope of Reg 1829/2003, it will not require a new authorisation under Reg 1334/2008/EC, as long as the new source is covered by an authorisation under the GM legislation and the flavouring complies with the specifications established under Reg 1334/2008/EC.

### 2.5.7 Requirements for the labelling of food containing flavourings

Regulation 1334/2008 provides detailed rules regarding the labelling of food to which flavourings have been added. These rules are a very important aspect of flavourings legislation and are considered separately in Chapter 4 of this guidance.

### 2.5.8 Monitoring and reporting requirements

Member States are legally required to monitor the consumption and use of flavourings on the Union list and the consumption of the substances listed in Annex III of Regulation 1334/2008 using a risk-based approach (Article 20 of the Regulation), and to report their findings to the European Commission and to EFSA at regular intervals. The FSAI monitors the Annex III substances on an ongoing basis through its chemical surveillance programme, and will expand the latter as appropriate to include other flavourings, although analysis of the many flavourings that may be used in food is a challenging task, particularly for the flavourings that occur naturally in food. It should be noted that it is also the responsibility of the food business operator to comply with the legislation regarding use of flavourings in food and to monitor their use in food he/she places on the market.

More reliable information on the use of flavouring substances in food can be obtained via the requirement in Article 19 for food business operators to report to the European Commission the amount of the substance added to foods in the Union over a particular period and information on the maximum levels used. The information on flavouring substances obtained in this way has been used by EFSA to estimate exposure to individual flavouring substances in carrying out its safety assessment as described in Chapter 3.

## Chapter 3. Assessment of Safety and Approval of Flavourings and Food Ingredients with Flavouring Properties

### 3.1 General Principles

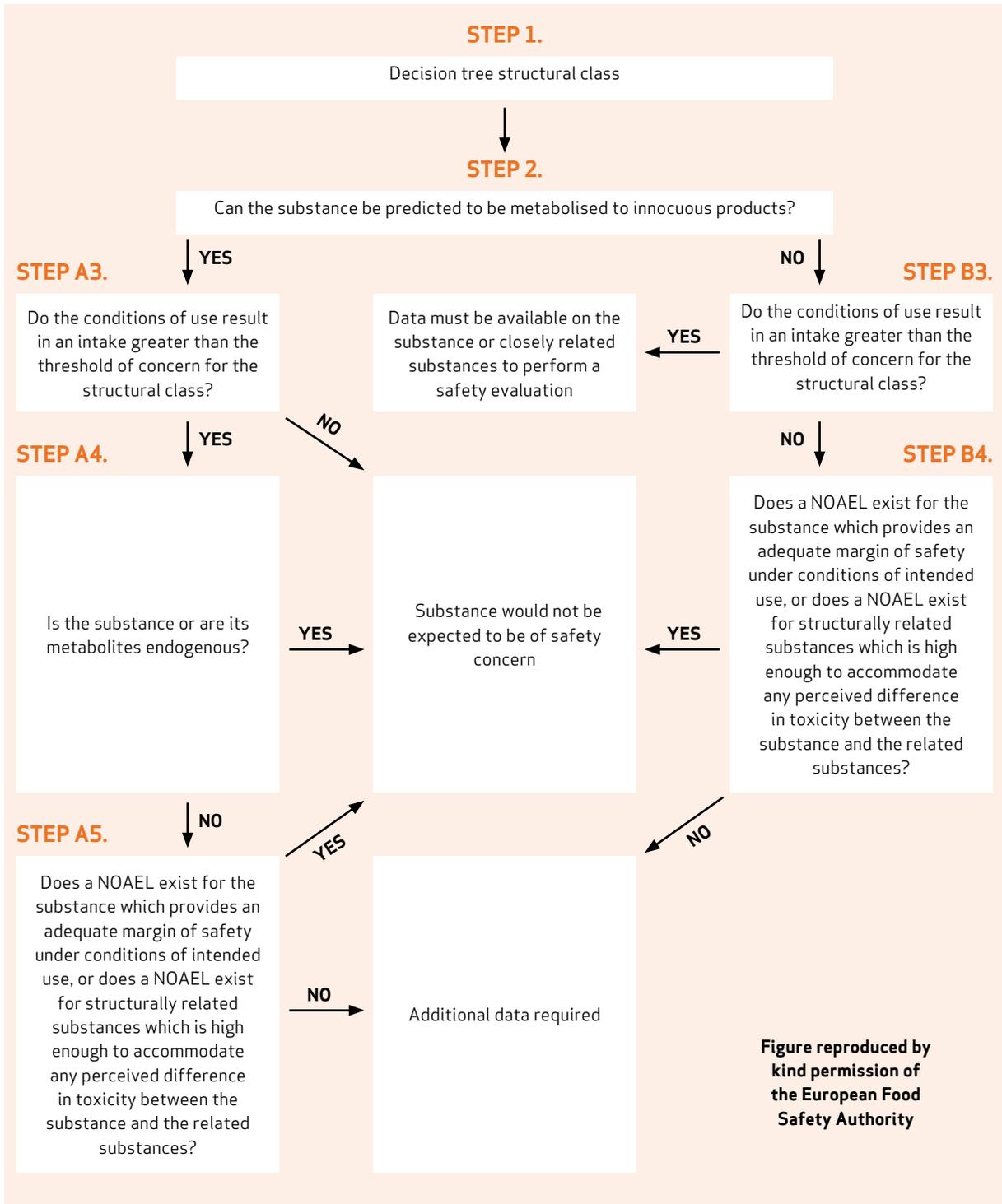
Safety evaluations of flavourings have been carried out in the EU by the SCF and more recently, (replacing the SCF), by EFSA. Similar evaluations have been carried out at an international level by the Joint Expert Committee on Food Additives (JECFA) under the auspices of the World Health Organization/Food and Agriculture Organization (WHO/FAO) and the Council of Europe Committee of Experts (CoE) on flavouring substances.

The JECFA programme of evaluation has been underway for over 30 years. JECFA has stated that “in view of the very large number of substances used as food flavouring agents and the fact that they are generally applied in low and self-limiting concentrations in foods, it is considered impractical and unreasonable to require that each food flavouring material be subjected to the same and extensive toxicological evaluation [as is applied to food additives] within a reasonable period” (WHO, 1987). For that reason, JECFA adopted an approach (the Procedure) which assessed flavouring substances used in food according to their chemical structure, based on the assumption that the handling (toxicokinetics, or absorption, distribution, metabolism and excretion) of structurally related compounds in the body would be similar (WHO, 1987; JECFA, 1995; JECFA, 1996; JECFA, 1997; JECFA, 1999). A read-across approach, in which data on one member or more members of the group can be used for the safety evaluation of the group as a whole, can therefore be applied.

JECFA has used this approach in the evaluation of a wide range of groups of flavouring substances including primary alcohols, aldehydes, carboxylic acids and esters, ring-substituted phenolic substances, amino acids, etc. The JECFA Procedure broadly involves an initial categorisation of the chemicals within a particular group into three possible subclasses dependent on further structural alerts within the molecule (the Cramer classes (Cramer *et al.*, 1978)). Class I contains flavourings with simple chemical structures, which are easily metabolised and excreted by the body, properties that are predictive of low oral toxicity. Class II contains flavourings that have structural features that are less innocuous, but are not suggestive of toxicity, while Class III comprises flavourings that have structural features that may be indicative of safety concern (Cramer *et al.*, 1978). The evaluation also takes the predicted exposure to the flavouring into consideration, based on the so-called ‘Maximised Survey-derived Daily Intake’ (MSDI), derived assuming that 10% of the population are consumers of the total annual production volume of the flavouring substance. This provides a per capita intake of the flavouring which can be compared with the so-called thresholds of concern (human exposure thresholds) which have been established for use in the Procedure. The thresholds of concern for the structural classes I, II, III are 1800, 540 or 90 microgram/person/day, respectively, and MSDI exposures below these thresholds are not considered to present a safety concern. An alternative exposure assessment methodology, the Theoretical Added Maximum Daily Intake (mTAMDI) values is based on the approach used by SCF up to 1995 (SCF, 1995), and is considered to provide a more realistic assessment of exposure.

In parallel, the EU SCF and the Council of Europe both developed guidelines for the safety evaluation of flavourings for use in foodstuffs, which were broadly similar to the approach developed by JECFA (SCF, 1991; Council of Europe, 1992) and initiated evaluation programmes. A more systematic evaluation programme initiated at EU level with the adoption of Regulation 2232/96 was based on the opinion of the Scientific Committee on Food (SCF, 1999), which in turn was derived from the evaluation procedure developed by JECFA. This procedure, which is shown schematically in Figure 3.1 (reproduced courtesy of EFSA), was used initially by SCF and more recently by EFSA for the evaluation of approximately 2,600 flavouring substances, reduced from the 2,800 substances initially declared for the Register. EFSA has divided the flavourings into 48 groups for evaluation, resulting in a series of Flavouring Group Evaluations (FGEs) which form the basis of the Union list. The EFSA groups are broadly similar to those evaluated by JECFA.

**Figure 3.1 Procedure for Safety Evaluation of Chemically Defined Flavourings**



As already indicated, the evaluations carried out by JECFA, Council of Europe, SCF and EFSA have been based on limited toxicological data providing evidence of safety of flavours. These data are not normally sufficient to establish a health-based Reference Value such as an Acceptable Daily Intake<sup>11</sup> (ADI), although a more comprehensive toxicological database is available for a small number of commonly used flavourings, e.g. menthol (occurring in mint plants and peppermint oil). For substances of potential health concern, e.g. those that are not predicted to be metabolised to innocuous products, and/or those for which the MSDI is greater than the threshold of concern for the structural class, a conclusion regarding safety can only be reached if there are toxicological data on one or more substances in the group that can be used to read-across to all substances in the group. EFSA in its evaluations, has identified a number of data gaps for groups of substances, particularly in relation to information on genotoxicity, and has requested additional information from the flavours industry before reaching a conclusion on safety. As already indicated, these substances have been indicated in the Union list introduced by Regulation 872/2012 by a footnote (1). If this information is not provided by industry in the timescale envisaged, these flavouring substances will be deleted from the Union list.

### 3.2 Safety Assessment of Smoke Flavourings

These flavourings are regulated under a stand-alone Regulation, Regulation 2065/2003, as described in more detail in section 2.2 of this guidance. The safety assessment of these products has been ongoing since 2005, with the objective of producing a positive list of smoke flavourings that can be used to flavour food in the EU, together with the maximum levels of use and the food categories in which they may be used. Finalisation of this list is anticipated in 2012. The procedure for regulation and evaluation of a smoke flavouring primary product (the active component of a smoke flavouring) is similar to that for flavourings in general, and the technical and toxicological data required to support a safety assessment of a primary product have been specified in an EFSA guidance document (EFSA, 2005). The technical data required include information on the identity and nature of the source material (wood species), details of the manufacturing process, chemical composition and specifications, data on batch-to-batch variability and stability, and on the content of PAHs. With respect to the toxicological data, the guidance document indicates that data for a safety assessment of a smoke flavouring primary product should include three *in vitro* genotoxicity tests (a test for induction of gene mutations in bacteria, a test for induction of gene mutations in mammalian cells *in vitro* and a test for induction of chromosomal aberrations in mammalian cells *in vitro*), as well as a 90-day feeding study in rodents. The guidance document also stipulates that positive results in any of the *in vitro* tests will normally require further assessment of genotoxicity *in vivo*.

Assessment of exposure to smoke flavourings, which are normally used at considerably higher levels in food than traditional flavourings with a consequent greater potential for exposure, uses two approaches (EFSA, 2009). The first, the Smoke Flavouring Theoretical Added Maximum Daily Intake (SMK-TAMDI), is based on an adaptation of the TAMDI approach to make it more specifically relevant for the use of smoke flavouring primary products in or on foods. The second, called Smoke Flavouring EPIC model (SMK-EPIC), makes use of the information on the consumption of smoked foods available from the European Prospective Investigation into Cancer and Nutrition (EPIC) study. Based on the outcome of the exposure assessment and the No Observed Adverse Effect Level (NOAEL) value derived from the 90-day feeding study in rats, EFSA has derived a Margin of Safety (MOS) between the NOAEL and the estimated human exposure estimate for the individual smoke flavouring primary products. Only those smoke flavouring primary products having a MOS in the range of 300 have been considered by the European Commission (acting on advice from EFSA) to be of sufficiently low safety concern that they could be considered for the positive list of smoke flavouring primary products.

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<sup>11</sup> An ADI is defined as: “an estimate of the amount of food additive, expressed on a body weight basis, that can be ingested daily over a lifetime without appreciable health risk.” See the FSAI’s *Guidance on Food Additives* (FSAI, 2011) for further information on the derivation of ADIs for food additives.

### 3.3 Approval Process for New Flavourings and Source Materials

As described in more detail in Section 2.5.5 of this guidance, now that the Union list has been adopted via Regulation 872/2012, any new flavourings and source materials to be added to the list will be evaluated and approved according to the procedures established in Regulations 1331/2008, 1334/2008 and 234/2011. An application for authorisation of a new flavouring or source material should be made to the European Commission, Health and Consumers Directorate-General (DG-SANCO), and companies requiring approval of a new product should contact the EU Commission in the first instance to check the administrative requirements and the procedure to be followed in submitting a dossier. Practical guidance for applicant companies on the submission of an application of a new food flavouring, food additive or food enzyme is available on the website of DG-SANCO, the arm of the Commission responsible for legislation on food improvement agents, including risk management measures. This guidance should be consulted for further information on the requirements [http://ec.europa.eu/food/food/FAEF/authorisation\\_application\\_en.htm](http://ec.europa.eu/food/food/FAEF/authorisation_application_en.htm)

Regulation 234/2011 lays down specific data required for the risk assessment and risk management of flavourings that should be included in the application dossier. These include, for the purposes of risk assessment, information on the following:

- (i) The manufacturing process of the flavouring
- (ii) Its specifications
- (iii) Where applicable, information on particle size, particle size distribution and other physicochemical characteristics
- (iv) Any information on the existing authorisations and evaluations
- (v) The proposed uses in food and proposed normal and maximum use levels in the categories according to the Union list or in a more specified type of product within the categories
- (vi) Data on dietary sources
- (vii) A dietary exposure assessment
- (viii) Biological and toxicological data

The biological and toxicological data should include information on structural/metabolic similarity to flavouring substances in an existing flavouring group evaluation (FGE), information on genotoxicity, and, where applicable, data on subchronic toxicity, developmental toxicity, chronic toxicity and carcinogenicity. This is a much more comprehensive data package than has been the case for the evaluations of flavourings that have been included in the Union list. It is anticipated that information on developmental toxicity, chronic toxicity and carcinogenicity will not normally be required, but will be conditional on the structural class of the flavouring (Class I, II or III) and the predicted exposure from the diet.

For the purposes of risk management, the information provided should include:

- (a) The identity of the flavouring, including reference to the existing specifications
- (b) Organoleptic properties of the substance
- (c) The proposed normal and maximum use levels in the food categories or in a more specific food belonging to one of these categories
- (d) The exposure assessment, based on normal and maximum intended use for each of the categories or products concerned

Additionally, EFSA has prepared a guidance document laying out the format of an application and listing the administrative and technical data required, and the range of toxicological tests generally required for the safety assessment of flavourings (EFSA 2010)<sup>12</sup>.

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<sup>12</sup> EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids; Draft Guidance on the data required for the risk assessment of flavourings. *EFSA Journal* 2010; 8(6):1623 <http://www.efsa.europa.eu/en/scdocs/doc/1623.pdf>

Under the common procedure laid down in Regulation 1331/2008, EFSA has nine months to issue their opinion following receipt of a valid application. However, where EFSA requests further information from applicants, this time period of nine months may be extended, and in a complex case which requires additional data/trials etc. the process of assessment could take several years.

If the flavouring is deemed to be safe by EFSA, the Commission will then initiate the process to add the substance to the Union list via a Commission Regulation. Under Regulation 1331/2008, the Commission must submit a draft Regulation containing the necessary measures for the authorisation of the additive to SCOFCAH for vote (the comitology procedure) within nine months of the EFSA opinion. Following the vote by SCOFCAH, the draft is forwarded to the European Parliament, which has a further three months to examine the proposal (the scrutiny procedure). As a result of this examination, the European Parliament may oppose legislative proposals from the Commission that would normally be adopted by the comitology procedure. The legal process laid down in Regulation 1331/2008 can thus take a minimum of 21 months before the flavouring is formally added to the Union list, at the point at which the Regulation containing the necessary measure has been published in the Official Journal and the date of application has been reached. Only at that time is the substance permitted for use in and on foods.

## Chapter 4. Labelling of Flavourings

### 4.1 General Labelling Requirements

Flavourings and food ingredients with flavouring properties should not be used in such a way as to mislead the consumer about issues related to, amongst other things, the nature, freshness, quality of ingredients used, the naturalness of a product or of the production process, or the nutritional quality of the product. The presence of flavourings in food should always be indicated by appropriate labelling. The use of flavourings and food ingredients with flavouring properties is subject to the general labelling provisions for food<sup>13</sup> as established by Council Directive 2000/13/EC<sup>14</sup> on the approximation of laws of the Member States relating to the labelling, presentation and advertising of foodstuffs, as amended, and to the more specific labelling requirements laid down in Regulation 1334/2008. Additionally, Regulation 1334/2008 provides specific labelling requirements for flavourings not intended for sale to the final consumer, i.e. for flavourings traded between one business and another. It also lays down requirements for the use of the term “natural” when describing a flavouring. The legal responsibility for the correct labelling of flavourings in a food product lies with the food business operator, as the primary person responsible for the composition of the product, including its flavour.

The labelling requirements apply to pre-packaged food or to the flavourings themselves, as supplied business to business, but not to unpackaged food.

It should be noted that foods legally placed on the market or labelled before 20 January 2011 (the date of application of Regulation 1334/2008) may be marketed until their date of minimum durability or ‘use-by’ date. Foods placed on the market after that date should comply fully with the labelling requirements of Regulation 1334/2008.

Under Article 6(6), 3rd indent, of Directive 2000/13/EC, flavourings must be identified in the list of ingredients on the label of the food in accordance with Annex III of the Directive. Annex III of Directive 2000/13/EC (as replaced by Article 29 of Regulation 1334/2008) allows for the generic term “flavouring(s)” or a more specific name or description of the flavouring, e.g. flavouring: menthol, lemon flavouring, meat flavouring, shrimp flavouring, etc, to be used on the label if the flavouring component meets one of the definitions laid down in Regulation 1334/2008 (see section 2.5.2 of this guidance). Figure 4.1. provides an example of the labelling of a food product which uses the generic term “flavouring”; this descriptor could also have contained the words “chicken flavouring” provided the source material had been chicken meat.

If however, the flavouring meets the definition of a smoke flavouring (2.5.2 (f)) and is used to impart a smoky flavour to the food, this must be specifically identified on the label. The ingredient list should contain the words “smoke flavourings” or “smoke flavouring(s) produced from “food(s) or food category or source(s)”, e.g. smoke flavouring produced from beech. It is no longer permissible to use only the descriptor “flavouring” on the label and smoke flavourings cannot be described as “natural”. These measures were introduced so that consumers could be informed if the smoky taste of a particular food is due to the addition of smoke flavourings

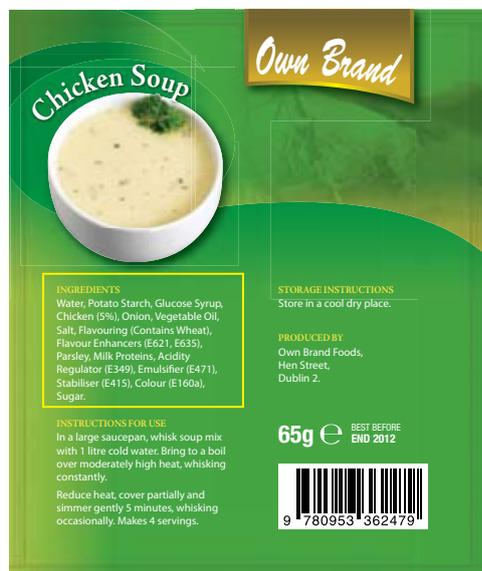
The composition of a “flavouring” may be extremely complex and contain a large number of components, flavours or otherwise, all adding to the final flavour characteristics of the product. Figure 4.2 provides an example of the composition of a peppermint flavouring, used to flavour mint sweets at a final concentration of 1%. It should be noted in this example that isolated menthofuran and pulegone are not permitted for direct addition to food (see section 2.5.3 of this guidance).

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<sup>13</sup> More information on the general labelling provisions for food can be found on the FSAI website, at: [http://www.fsai.ie/legislation/food\\_legislation/labelling\\_of\\_food.html](http://www.fsai.ie/legislation/food_legislation/labelling_of_food.html)

<sup>14</sup> Directive 2000/13/EC has now been replaced by Regulation 1169/2011, which came into effect on the 13th December 2011. It will apply from 13 December 2014, with the exception of point (l) of Article 9(1) (mandatory nutrition declaration), which shall apply from 13 December 2016, and Part B of Annex VI (specific requirements regarding the designation of minced meat), which will apply from 1 January 2014.

Figure 4.1 Example of labelling of a food product including the generic term “flavouring”

**INGREDIENTS**

Water, Potato Starch, Glucose Syrup, Chicken (5%), Onion, Vegetable Oil, Salt, Flavouring (Contains Wheat), Flavour Enhancers (E621, E635), Parsley, Milk Proteins, Acidity Regulator (E349), Emulsifier (E471), Stabiliser (E415), Colour (E160a), Sugar.

Figure 4.2 Composition of a peppermint flavouring

Component	Concentration (%)
Peppermint oil	2.50
Water	77.50
Alcohol (ethyl alcohol)	20.00
% content of main flavouring substances contributed by the peppermint oil component (2.5%)	
Menthol	0.75 – 1.38
Menthone	0.35 – 0.80
Menthyl acetate	0.07 – 0.25
Isomenthone	0.04 – 0.25
Menthofuran	0.025 – 0.23
Cineole	0.09 – 0.35
Pulegone	< 0.1
Carvone	< 0.025
Isopulegol	< 0.005
$\alpha$ -pinene, $\beta$ -pinene	< 0.001
Etc.	

## 4.2 Use of the Words “Natural” Flavouring on the Label

The provisions regarding the use of the word “natural” applied to declaration of flavourings in the ingredients list have changed substantially via Regulation 1334/2008. Recital 26 of the Regulation states that:

**“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 standardisation or to give a, for example, more fresh, pungent, ripe or green note to the flavouring. 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, for example cacao extract in which other natural flavourings have been added to impart a banana note.”**

The definition of natural flavouring substance (see section 2.5.2) requires that such substances must have been identified in animal, vegetable or microbial material and have been isolated from this source material either in its raw state or after it has been processed by a traditional food preparation method such as chopping, steeping or squeezing. Isolation of a natural flavouring substance from its source can only be carried out using physical, enzymatic or microbiological processes, as opposed to, e.g. extraction using chemical methods. Annex II of the Regulation, as also shown in Table 2.5, contains a list of traditional food preparation methods that can be used in the production of natural flavouring substances.

The previous legislation (Directive 88/388/EEC) defined “flavouring substance” as a defined chemical substance with flavouring properties which is obtained by:

- (i) Appropriate physical processes (including distillation and solvent extraction) or enzymatic or microbiological processes from material of vegetable or animal origin either in the raw state or after processing for human consumption by traditional food-preparation processes (including drying, torrefaction and fermentation)
- (ii) Chemical synthesis or isolated by chemical processes and which is chemically identical to a substance naturally present in material of vegetable or animal origin as described in (i)

This definition encompassed natural flavouring substances, so-called nature identical flavouring substances and artificial flavouring substances, all three terms being used to indicate the presence of a flavouring in food. Under Regulation 1334/2008, specific rules are now laid down (in Article 16) for the use of the word “natural” in relation to flavourings. The previous text of Annex III of Directive 2000/13/EC dealing with this issue which, together with the definition of flavouring substance in Directive 88/388/EEC, had led to some confusion and misinterpretation on the use of the term “natural”. This has now been replaced by a provision indicating that the term “natural” for the description of flavourings shall only be used in accordance with Article 16 (reflecting Recital 26, shown above).

Article 16(4) specifies 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 (which has to be a natural flavouring substance or flavouring preparation) has been obtained exclusively or by at least 95% by w/w from the source material. This is the so-called 95% rule and means, e.g. that a 95% of a “natural vanilla flavouring” must have been obtained from vanilla pods. Under the previous legislation (Directive 88/388/EEC) there was also a provision that to use the term “natural” the flavouring should have been produced predominantly from a natural source, however the cut-off value for use of the term was 90% rather than 95%. As illustrated in Figure 4.3, Regulation 1334/2008 requires that 100% in total of the flavouring component must have been derived from natural sources. This is made up of the named flavour which must be at least 95% from the identified source and the remaining 5% of a natural flavouring obtained from other sources should only be used for standardisation or, for example, to provide a more fresh, pungent, ripe or green note to the flavouring.

**Figure 4.3 Requirements for the composition of a flavouring used in a food in order for the flavouring to be described as “natural”**

- The flavouring components must be derived 100% from natural sources
- The named flavour(s), e.g. vanilla flavour, must be derived at least 95% from the identified source material, e.g. vanilla pods
- Up to 5% of other flavouring components are allowed, e.g. spearmint oil, but these must also be derived from natural sources

Standardisation may be necessary to adjust natural variations in the flavour-profile to ensure a consistent quality while, for example, addition of a fresh note could be achieved by addition of 0.01% of spearmint oil and a pungent note by addition of 1% of red pepper oleoresin. Several natural sources may be included in the 5% of a natural flavouring obtained from other sources provided that the total does not exceed 5%. Other categories of flavouring materials, e.g. smoke flavouring, cannot be present, although the presence of other non-natural materials, e.g. solvents or additives such as carriers in the flavour (see section 2.5.2), does not affect the natural status. The term “natural flavouring” alone is not allowed.

Other provisions of Article 16 lay down that:

- (i) *“The term “natural” for the description of a flavouring may be only used if the flavouring component comprises only flavouring preparations and/or natural flavouring substances”* (compliant with the 95% rule outlined above) (Art. 16(2))

The definition of flavouring preparations under Regulation 1334/2008 encompasses any flavouring other than a flavouring substance, produced from source materials by the processes laid down in the definition for natural flavouring substance and flavouring preparations are therefore by definition natural.

- (ii) *““natural flavouring substance” may only be used for flavourings in which the flavouring component contains exclusively natural flavouring substances”*.

An example of a natural flavouring substance is the flavouring substance limonene obtained from oranges. Looking at the more complex case of an orange flavouring 100% sourced from oranges and containing limonene, this could variously be described as “natural orange flavouring”, or “natural flavouring substance (limonene)” (in the case of natural limonene obtained from oranges). If, on the other hand, the flavouring contains limonene produced by chemical synthesis, the labelling should only show “flavouring” or “orange flavouring”. “Flavouring (contains limonene)” would also be acceptable.

An example of labelling for a food product containing natural flavouring is shown in Figure 4.4.



Figure 4.4 Example of labelling of a food product including the term “natural .... flavouring”



It should be noted in relation to the label above that the application of the labelling phrase “Natural ..... flavouring” only applies to the ice-cream component of the food product (containing natural vanilla flavouring, > 95%). While it might have been anticipated that the ingredient list for the cherry sauce might have included “Natural cherry flavouring”, this is not permissible since the flavouring does not derive at least 95% from cherries. Rather, it contains a number of natural fruit flavourings, any of which do not dominate the ultimate cherry flavour of the sauce. The term “natural flavouring” alone, without reference to the source material, as used in the example above, may only be used if the flavouring component(s) are derived from different source materials and where a reference to the source materials would not reflect their flavour or taste (Article 16(6) of Regulation 1334/2008). A further example would be a flavouring for which the predominant taste was mango but which had been at least 95% derived from passion fruit and papaya. The term “natural flavouring” is no longer permissible as a general descriptor for flavourings from natural sources, but can only be used in accordance with Article 16(6).

Further information regarding the labelling of the flavourings in the ice-cream/cherry sauce product is presented in Figure 4.5 below.

Figure 4.5 Further information regarding the labelling of a food product including the term “natural .... flavouring”

#### INFORMATION

##### 1. Ice-cream

The ice-cream is described as ‘**vanilla flavoured**’ and the ingredients list describes it as containing ‘natural vanilla flavouring’.

To use the term ‘**natural vanilla flavouring**’ the flavour compound must be 95% vanilla extract with the flavour being **recognisable** as vanilla.

##### Points to note:

If the flavouring component from vanilla is **below 95%** and the flavour is recognisable as vanilla the label should say “**Natural vanilla flavouring with other natural flavourings**”.

If this is the case the name of the ice-cream can be described as ‘**vanilla flavoured**’

However, only if the source of the flavouring:

- is vanilla but is **not recognisable** as vanilla, or
  - is not derived from vanilla at all
- can the term “**natural flavouring**” be used.

If this is the case the name of the ice-cream **cannot** be described as ‘**vanilla flavoured**’ but should be called ‘**vanilla flavour**’.

##### 2. Cherry sauce

The cherry sauce in the ingredients list contains ‘**natural flavourings**’

For this to be correct:

- there needs to be no cherry derived components in the flavouring or
- the source of the flavouring should not be recognisable as cherry

Where the natural flavouring has been derived from two source materials, e.g. cherry and raspberry, the label may indicate this provided the two flavouring components together have been produced to a total of at least 95% from the source materials. The major contributor by weight should be mentioned first and both flavours should be recognisable in the food. Thus, in the example provided above, if the flavouring in the sauce had been derived from cherry and raspberry, with both flavours being discernible but with cherry being the main contributor, the label should contain the descriptor “natural cherry and raspberry flavouring”.

If the natural flavouring (cherry) does not comply with the 95% rule, but still has a predominant identifiable flavour although other natural flavourings have also been included, e.g. other red fruits, Article 16(5) applies:

*“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 be easily recognised.”*

This description will be used for flavourings with a predominant flavour, e.g. raspberry but where other source materials have also been used in the production, e.g. other red fruits. The descriptor may then be “natural cherry flavour with other natural flavourings” (but see Figure 4.6 below). The term “natural flavouring” alone is not allowed.

Depending on the proportions of the various natural flavourings a number of labelling options exist, as illustrated in Figure 4.6.

**Figure 4.6 Options for labelling when several flavouring components are used in combination**

Composition of the flavouring component

- **60% derived from cherry**
- **35% derived from raspberry**
- **5% derived from pomegranate** (flavour not discernible)

**Possible labelling options**

- Natural cherry and raspberry flavouring
- Natural cherry flavouring with other natural flavourings (providing that cherry is the recognisable flavour)
- Natural raspberry flavouring with other natural flavourings (providing that raspberry is the recognisable flavour)
- Natural flavouring (only if neither cherry or raspberry is recognisable, unlikely)
- Natural fruit flavourings
- Cherry and raspberry flavourings
- Flavourings

In achieving the desired flavour in a food product, a number of different flavourings may be used, both natural and non-natural. Assuming that the 95% rule does not hold, a complex situation arises whereby the natural flavouring may still be described as such on the label, but the presence of the non-natural flavour must be identified in accordance with the labelling rules laid down in Council Directive 2000/13/EC and with the more specific labelling requirements laid down in Regulation 1334/2008. An example of possible options for the labelling of a food product which contains both natural and non-natural flavouring is provided in Figure 4.7.

**Figure 4.7 Example of labelling of a food product which contains both natural and non-natural flavouring**

**EXAMPLE: Cake produced using a natural ginger flavour from one supplier and a small amount of non natural vanilla flavour from a second supplier**

**POSSIBLE LABELLING**

Natural ginger flavouring, vanilla flavouring **or** Natural ginger flavouring, flavouring

**However if the same flavourings were bought as a combination from the same supplier, label would say:**

“Ginger and Vanilla Flavouring” or just “Flavouring”

### 4.3 Labelling of Flavourings not intended for Sale to the Final Consumer

In addition to the general rules related to labelling of flavourings in food and the specific rules regarding labelling of natural flavourings, Regulation 1334/2008 lays down requirements for the labelling of flavourings not intended for sale to the final consumer, as described in this section, and for the labelling of flavourings intended for sale to the final consumer (section 4.4).

Flavourings not intended for sale to the final consumer, e.g. those traded between food business operators, whether sold singly or mixed with each other and/or with food ingredients, must be labelled with the information provided for in Articles 15 and 16 of Regulation 1334/2008. The labelling must be easily visible, clearly legible and indelible, and in a language easily understandable to purchasers of the product (normally food business operators).

Article 15(1) of Regulation 1334/2008 requires that the packaging or containers of such flavourings must bear the following information:

- (a) The sales description: either the word ‘flavouring’ or a more specific name or description of the flavouring
- (b) The statement either ‘for food’ or the statement ‘restricted use in food’ or a more specific reference to its intended food use
- (c) If necessary, the special conditions for storage and/or use
- (d) A mark identifying the batch or lot
- (e) In descending order of weight, a list of:
  - (i) The categories of flavourings present and
  - (ii) The names of each of the other substances or materials in the product or, where appropriate, their E-number
- (f) The name or business name and address of the manufacturer, packager or seller;
- (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 Regulation 1334/2008 or other relevant Union law
- (h) The net quantity
- (i) A date of minimum durability or ‘use-by’ date
- (j) Where relevant, information on a flavouring or other substances referred to in Article 15 and listed in Annex IIIa to Directive 2000/13/EC as regards the indication of the ingredients

The information required in points (e) and (g) above need only be provided on the accompanying documents relating to the consignment of the food additive, whether it is sold singly or mixed with other food additives and/or with other food ingredients provided that the indication 'not for retail sale' appears on an easily visible part of the packaging or container of the product in question. Where food additives are supplied in tankers, all of the information may be provided on the accompanying documents relating to the consignment which are to be supplied with the delivery.

The rules related to labelling of natural flavourings, as described in section 4.2, must also be complied with in the case of flavourings not intended for sale to the final consumer.

#### 4.4 Labelling of Food Additives intended for Sale to the Final Consumer

In addition to the labelling requirements set out in Directive 2000/13/EC<sup>15</sup> on the labelling, advertising and presentation of foodstuffs, in Directive 2011/91/EU on indications or marks identifying the lot to which a foodstuff belongs and in Regulation 1829/2003 on genetically modified food, flavourings sold singly or mixed with each other and/or other food ingredients which are intended for sale to the final consumer may be marketed only if their packaging contains the following information:

- (a) Either the statement 'for food' or the statement 'restricted use in food' or a more specific reference to its intended food use
- (b) Reference to their intended food use, which must be easily visible, clearly legible and indelible

The rules related to labelling of natural flavourings, as described in section 4.2, must also be complied with in the case of flavourings intended for sale to the final consumer.

#### 4.5 Labelling Requirement for Foods containing Flavourings associated with certain Health Effects

When certain allergenic foodstuffs are used as source material for flavourings, the requirements of Directive 2000/13/EC related to allergen labelling also apply. Annex IIIa of Directive 2000/13<sup>16</sup> contains a list of those substances that must be indicated on the label as well those substances that may be excluded from the 'allergen' labelling requirement. The following ingredients must be indicated on the label if they are present in a food product, including a flavouring<sup>17</sup>:

- Cereals containing gluten, i.e. wheat, rye, barley, oats, spelt, kamut or their hybridised strains) and products thereof, except:
  - Wheat-based glucose syrups including dextrose
  - Wheat-based maltodextrins
  - Glucose syrups based on barley
  - Cereals used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages
- Crustaceans and products thereof
- Eggs and products thereof
- Fish and products thereof, except:
  - Fish gelatine used as carrier for vitamin or carotenoid preparations
  - Fish gelatine or Isinglass used as fining agent in beer and wine

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<sup>15</sup> Directive 2000/13/EC has now been replaced by Regulation 1169/2011, which came into effect on the 13th December 2011. It will apply from 13 December 2014, with the exception of point (l) of Article 9(1) (mandatory nutrition declaration), which shall apply from 13 December 2016, and Part B of Annex VI (specific requirements regarding the designation of minced meat), which will apply from 1 January 2014

<sup>16</sup> Annex IIIa of Directive 2000/13 was amended by Directive 2007/68/EC, but none of these amendments were relevant to flavourings

<sup>17</sup> Not all of these materials are used as flavourings, but the list is provided here for completeness

- Peanuts and products thereof
- Soybeans and products thereof, except:
  - Fully refined soybean oil and fat
  - Natural mixed tocopherols (E306), natural D-alpha tocopherol, natural D-alpha tocopherol acetate, natural D-alpha tocopherol succinate from soybean sources
  - Vegetable oils derived phytosterols and phytosterol esters from soybean sources
  - Plant stanol ester produced from vegetable oil sterols from soybean sources
- Milk and products thereof (including lactose), except:
  - Whey used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages
  - Lactitol
- Nuts, i.e. almonds (*Amygdalus communis* L.), hazelnuts (*Corylus avellana*), walnuts (*Juglans regia*), cashews (*Anacardium occidentale*), pecan nuts (*Carya illinoensis* (Wangenh.) K. Koch), Brazil nuts (*Bertholletia excelsa*), pistachio nuts (*Pistacia vera*), macadamia nuts and Queensland nuts (*Macadamia ternifolia*), and products thereof, except:
  - Nuts used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages
- Celery and products thereof
- Mustard and products thereof
- Sesame seeds and products thereof
- Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/litre expressed as SO<sub>2</sub>
- Lupin and products thereof
- Molluscs and products thereof

Any ingredient from the above list used in the production of a food and still present in the finished product even if in an altered form must be indicated on the label with a clear reference to the name of the ingredient from which it originates. An example of this is provided in Figure 4.1, where the label stated “Flavouring (contains wheat)”.

Quinine and caffeine are flavourings which may cause hypersensitivity or temporary behavioural changes and they must be declared in the list of ingredients, e.g. “flavouring: quinine”. An indication of the amount of caffeine, where this is in excess of 150mg/l, must be included in beverages which do not naturally contain caffeine. The statement “High caffeine content” followed, in brackets and in accordance with Article 13(2) of Directive 2000/13/EC, by the caffeine content expressed in mg/100 ml. This information must appear on the label in the same field of vision as the name under which the product is sold. The statement will be expanded under the new Labelling Regulation 1169/2011. When this is in force, two different statements will apply to beverages and other foods containing caffeine. The first of these applies to beverages except those based on tea/coffee, the text of which is as follows: ‘*High caffeine content. Not recommended for children or pregnant or breast-feeding women*’ in the same field of vision as the name of the beverage, followed by a reference in brackets and in accordance with Article 13(1) of this Regulation to the caffeine content expressed in mg per 100ml. The second is for foods other than beverages with caffeine added for physiological purposes, as follows: ‘*Contains caffeine. Not recommended for children or pregnant women*’ in the same field of vision as the name of the food, followed by a reference in brackets and in accordance with Article 13(1) of this Regulation to the caffeine content expressed in mg per 100g/ml. In the case of food supplements, the caffeine content shall be expressed per portion as recommended for daily consumption on the labelling.

Presently, labelling rules do not require the specific naming of other flavourings in ingredient lists.

## 4.6 Other Labelling Requirements

In addition to the labelling requirements imposed by Directive 2000/13/EC, Regulation 1334/2008 and the other legal instruments mentioned above, there is other potentially applicable EU legislation such as Regulation 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures, laws, regulations or administrative provisions regarding weights and measures or legislation on the transport of chemicals substances and preparations. Food business operators should be aware of these additional requirements and the need to label products for purposes other than food use.

These labelling requirements may vary dependent on whether the flavouring is already present in a foodstuff intended for sale to the final consumer, or whether it is in a form intended for sale to and use by industry, e.g. a concentrate or high purity form, but which is not intended for sale to the final consumer.

## Chapter 5. Enforcement

In Ireland, the body responsible for the enforcement and execution of the legislation on flavourings is the FSAI, in cooperation with the State agencies that work under service contact to the FSAI, in particular, the HSE.

## Abbreviations/Glossary

<b>EFSA</b>	European Food Safety Authority
<b>EU</b>	European Union
<b>FIAP</b>	Food Improvement Agents Package
<b>GM</b>	Genetically Modified
<b>GMO</b>	Genetically Modified Organism
<b>GMM</b>	Genetically Modified Microorganism
<b>JECFA</b>	Joint Expert Committee on Food Additives
<b>PARNUTS</b>	Foods for Particular Nutritional Uses
<b>SCF</b>	Scientific Committee for Food
<b>SCOFCAH</b>	Standing Committee on the Food Chain and Animal Health
<b>Union</b>	The economic and political union of 27 Member States created by the Treaty of Lisbon

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<sup>18</sup> References to Directives and Regulations cited in this guidance have not been included in this Reference list. They may be readily accessed from the FSAI website, under "Legislation" <http://www.fsai.ie/legislation.html>





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