

EFFA Guidance on Flavourings with Modifying Properties (FMPs)

Preliminary remarks

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

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

The Commission Guidance Note as well as the EFFA document FL/12/44C [Annex I²] submitted by EFFA in the course of the editorial discussions at EU-level relate to chemically defined substances in the context of their notification. However, it appears that food operators increasingly raise specific questions relating to the correct use and the appropriate labelling of flavourings with modifying properties in general.

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

Supplemental guiding elements

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

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

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

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

Definitions and Terminology

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

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

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

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

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

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

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

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

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

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

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

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

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

Determination of the functional effects

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

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

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

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

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

Two sensory tests should be applied:

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

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

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

⁵ Annex II: Sensory Profiling

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

Maximum advised use levels

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

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

DISCLAIMER

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

Everyone should be aware of and fulfill all their obligations under applicable national and European laws and regulations. The guidance given by EFFA does not relieve members or any other persons of their obligations⁷ under those laws and regulations and members and any other persons should always satisfy themselves in any particular instance that the guidance provided by EFFA can be properly followed.

EFFA Secretariat – 4 March 2015

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

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