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

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Contents

IMPORTANT DISCLAIMER

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

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

1. Purpose

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

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

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

2. Flavouring substances with modifying properties

Legislative framework:

The term "flavourings" is defined in Article 3, paragraph 2 of Regulation (EC) No 1334/2008[1] on flavourings:

> *(a) 'flavourings' shall mean products:*
> *(i) not intended to be consumed as such, which are added to food in order to impart or modify odour and/or taste;*

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

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

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

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

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

[1] OJ 354, 31.12.2008, p.34

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

How are flavouring substances with modifying properties used?

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

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

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

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

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

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

3. Flavour enhancers

Legislative framework:

The definition of "flavour enhancer" is laid down in point 14 of Annex I of Regulation (EC) No 1333/2008[2] on food additives:

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

[2] OJ L 354, 31.12.2008, p. 16

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

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

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

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

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

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

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

"2. This Regulation shall not apply to the following substances unless they are used as food additives:
.../...
(e) flavourings falling within the scope of Regulation (EC) No 1334/2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods."

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

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

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

How are flavour enhancers used?

Flavour enhancers are added to food:

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

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

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

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

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

Flavour enhancers

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

Flavour substances with modifying properties

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

  Notes on Neohesperidine DC:

  1. Neohesperidine DC (E959) is also a flavour enhancer authorised under Regulation 1333/2008 on additives at a level of up to 5 mg/kg.

  2. Neohesperidine DC (E959) is also authorised as a sweetener under Regulation 1333/2008 for uses at levels between 10 to 150 mg/kg.

5. Consequences following the classification

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

- Chemically defined substances that modify the taste and/or the odour of a food are evaluated, authorised and used in accordance with the flavouring Regulation (EC) No 1334/2008 (section 2).

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

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

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

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

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

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