

EFFA Guidance Document on The determination of Food Sources under the EU-Regulation on Flavourings

Key messages:

- The European Flavouring Regulation distinguishes between source materials, which can be considered as “food” and source materials other than food.
- Certain categories of flavourings, if obtained from “non-food sources”, have to be evaluated and approved by EFSA (European Food Safety Authority).
- Flavourings do not fall under the scope of the Novel Food Regulation.
- The current Guidance Document provides elements to assess and determine whether a certain Source Material (SM) can be regarded as a “Food SM” or a “non-Food SM”.

1. Preliminary remarks

The Regulation (EC) No 1334/2008 on flavourings (hereinafter “the Flavouring Regulation”) distinguishes between source materials, which can be considered as “food”¹ (hereinafter “food sources”) and source materials other than food (hereinafter “non-food-sources”), see Article 3(2)(j) of the Regulation.

This distinction is highly relevant, insofar as certain flavouring categories (i.e. flavouring preparations, thermal process flavourings and flavour precursors) have to be evaluated and approved by the European Food Safety Authority (EFSA) pursuant to Article 9 of the Regulation whenever they have been obtained from “non-food-sources”.

It is important to note that flavourings do not fall under the scope of the Regulation (EU) 2015/2283 on Novel foods (*Art. 2(2)(b)(iii)*).

According to Article 3(3) (and Recital (16)) of the Flavouring Regulation source materials, for which hitherto (until the date of application of the Regulation, i.e. 20.01.2011) there is significant evidence of use for the production of flavourings, shall also be considered as food for the purpose of the Regulation. EFFA is of the view that all sources which have been used for the production of flavourings before the date of application of the Regulation (i.e. 20.01.2011) and for which this use can be evidenced, should therefore be considered as “food-sources”.

In cases where the evidence of use cannot be demonstrated the manufacturer will have to assess the status of a given source material and, where indicated, file a dossier for evaluation under the Common Authorisation Procedure (CAP) under Regulation (EC) No 1331/2008.² The present document provides a set of elements for the assessment of the status of source materials.

¹ According to Article 2 of Regulation 178/2002 “food” is considered as any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans.

² Regulation (EC) No 1331/2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 354/1 of 31.12.2008)

2. Determination of the food status of a source material (hereinafter referred to as SM)

2.1 Proven record or evidence of use as food

- The SM is generally recognized as food respectively food ingredient within EU.
- The [Novel Food Catalogue](#) may be consulted in case there is a doubt whether the SM is recognized as food within EU (keeping in mind that it's a non-exhaustive list and a living document).
- Approval as Novel Food is considered as proven record for the food status (see Commission Implementing [Regulation \(EU\) 2017/2470](#)).
 - In Case of a Novel Food authorized as traditional food from a third country then it can be regarded as an acceptable "food source material" for flavourings.
 - EFTA considers that the authorization of use of a Novel Food as a food supplement alone is not sufficient to justify the food source character of this NF in the sense of the Flavouring Regulation.
- The SM is listed in at least one national inventory list of foods (such as the German "BVL-Stoffliste") or other inventory (e.g. the ["THIE Inventory of Herbs Considered as Foods"](#)).

2.2 Proven record or evidence of use as source material

- The SM has been used for the production of flavourings before 20 January 2011.
- The SM is listed in an inventory of recognized source materials compiled from different regulatory and/or assessment bodies around the world. To the best of our knowledge the following lists are currently available: COE "Blue Book", FEMA-GRAS-List, FDA-Lists, Japan FSL (Food Sanitation Law), China CPL (Chinese Positive List in GB 2760-2011). The IOFI Global Reference List (GRL) is publicly available and includes a compilation of COE, FEMA and FDA listed materials. For the IOFI membership there is a comprehensive IOFI data base available that also contains information on other references.
- The company has the relevant documentation to demonstrate the "history of use", e.g. invoices of the SM or the flavouring preparation from this SM, manufacturing records, flavouring production records, etc.

2.3 Other elements

You will find hereafter a set of elements, intended to help a company to assess the status of a given SM for which there is no proven record nor evidence of use as described above:

- The SM is listed in the inventory compiled by the European flavour industry, the so-called DVAI database, which provides a search tool dedicated to find one or more references (scientific literature) related to a given source material, which evidence their use as food material. Please note: The listing of a source material in this inventory does not imply that this is sufficient proof of use of the corresponding source material for the production of flavourings.
- "Culinary know how": Information of uses described in recipes published in known culinary reviews, cook books, e.g. "Larousse Gastronomique", and menus from restaurants, could be indicators as well.
- Any other elements / evidence which could be used as an identification of the SM as food.

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EFFA Secretariat

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