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## The determination of Food Sources under the new EC-Regulation on Flavourings

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### *Preliminary remarks*

The new Regulation (EC) No 1334/2008 on flavourings (hereinafter “the Regulation”) introduces a distinction between source materials, which can be considered as “food”<sup>1</sup> (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”.

According to Article 3 (3)<sup>2</sup> of the Regulation source materials, for which hitherto (until the date of application of the Regulation, i.e. the 20 January 2011) there is significant evidence of use for the production of flavourings, shall be considered as food for the purpose of the Regulation. EFA is of the view that all sources which have been used for the production of flavourings anywhere in the world 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.<sup>3</sup> The present document provides a set of elements for the assessment of the status of source materials.

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<sup>1</sup> 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.

<sup>2</sup> See also whereas 16 of the Regulation.

<sup>3</sup> 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)

## ***Qualification of the source material (hereinafter referred to as SM)***

### **1) Evidence of use**

- The SM has been used for the production of flavourings before 20 January 2011.
- The company needs 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) 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 evidence of use as described under 1):

#### *a) Proven record*

- The SM is listed in an inventory of recognised 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).

#### *b) Other indicators*

- 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.
- Clear identification of the SM as food: This identification could be conducted by independent experts, e.g. botanic(al) experts.
- “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.

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<sup>4</sup> 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).