

Partenariat Analyse Authenticité Arômes



Analytical controls and regulatory compliance of natural flavourings

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This educational document has been prepared by the Scientific Committee of the Partenariat Analyse Authenticité Arômes (Flavouring Authenticity Analysis Partnership or P3A). P3A was set up by SNIAA (French Flavour Association) in conjunction with several analytical laboratories with the aim of boosting confidence both in the results produced by analytical laboratories and the products offered by flavouring manufacturers.

Members of P3A are indeed frequently called upon to conduct analyses to confirm the compliance of natural flavourings.

Regulatory compliance for natural flavourings is a two-stage process:

- Compliance of the natural status of the flavouring: In order to be qualified as 'natural', the flavouring in question must first meet the requirements of Article 16.2 of the "Flavouring" Regulation (EC) 1334/2008.
- Compliance of the sales description with the definitions set out in Articles 16.4, 16.5 and 16.6 of the 'Flavouring' Regulation, particularly where the term 'natural X flavouring' (X being the source material of the flavouring) is used.

1. Expert assessment of the natural status of a flavouring

1.1. Summary of the relevant regulation

1.2. Controlling the compliance of natural status flavourings: role of the manufacturers

1.3. Checking the compliance of natural status flavourings: role of analytical controls

2. Assessing the compliance of a sales description that may refer to the name of a flavouring source material

2.1. Regulatory aspects

2.2. Ensuring the compliance of flavourings whose description may include the name of a flavouring source material

2.3. Checking the compliance of a sales description 'natural X flavouring': role of analytical controls

3. Conclusion

1. Expert assessment of the natural status of a flavouring

1.1. Summary of the relevant regulation

The term 'natural' may only be used where the flavouring part of the flavouring contains exclusively flavouring components as mentioned/listed in Article 16.2 of the "Flavouring" Regulation (EC) 1334/2008 (reproduced below), i.e. natural flavouring substances (chemically defined substances (CDS)), and/or flavouring preparations (FP or Natural Complex Substances – NCS).

2. The term 'natural' for the description of a flavouring may only be used if the flavouring component comprises only flavouring preparations and/or natural flavouring substances.

It is therefore important to note that the composition of the non-flavouring part is not taken into account

when determining the natural status of a flavouring. Article 3.2. of the same regulation defines these flavouring components (Art. 3.2. c and d respectively); furthermore, Art. 3.2.k and Annex II contain additional information on the processes by which they can be obtained (reproduced below).

c) 'natural flavouring substance' shall mean 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' shall mean 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;

k) 'appropriate physical process' shall mean 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, organo-metallic reagents and/or UV radiation

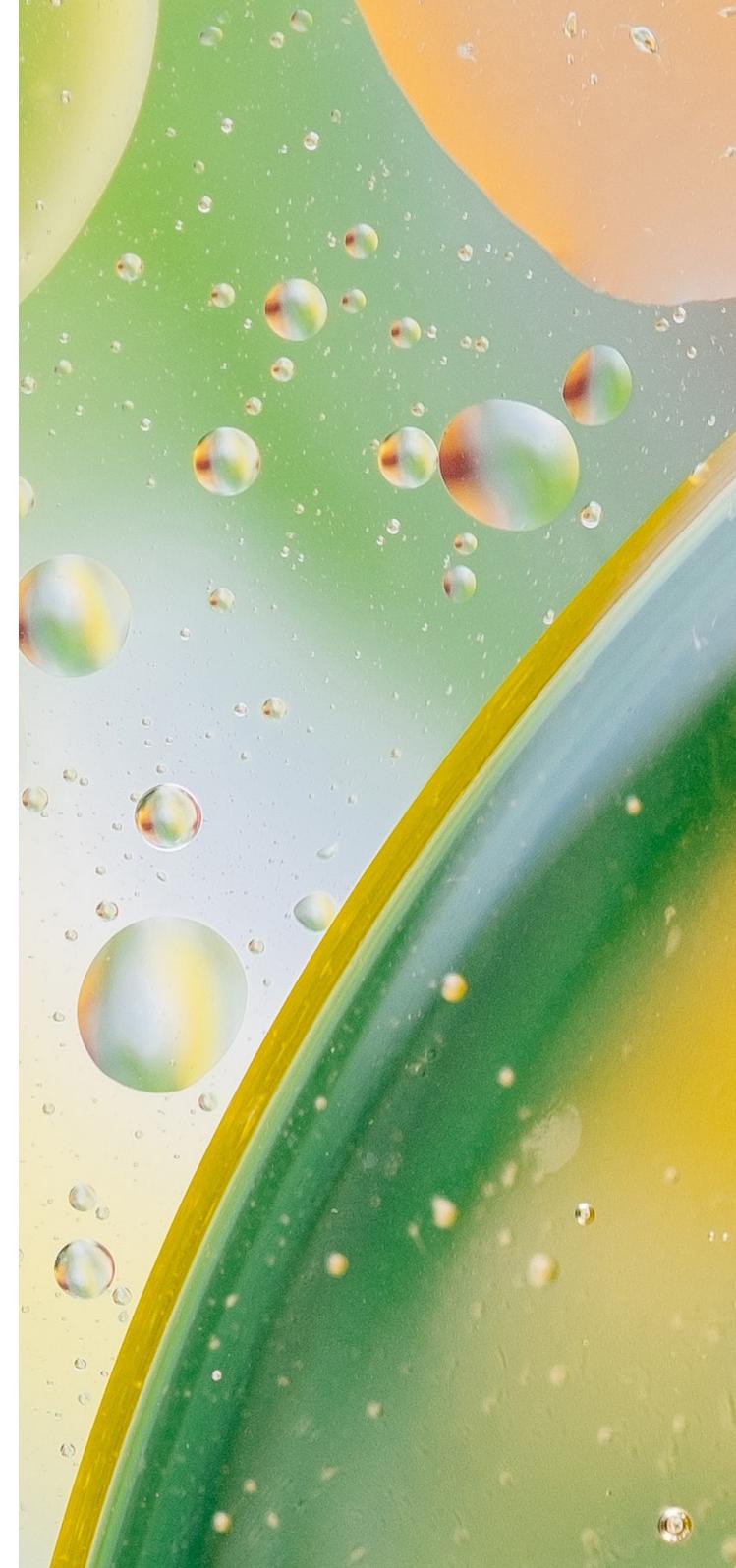
1.2. Controlling the compliance of natural status flavourings– role of the manufacturers

Operators are required to comply with three general obligations (Regulation (EC) 178/2002, Articles 17. 1. and 18):

- Placing on the market of only compliant food products;
- Self-checking of the compliance of these foods (use of natural flavouring components (CDS and/or NCS) and formulation in compliance with Article 16.2 of the Flavouring Regulation);
- Guaranteeing product traceability.

Manufacturers implement appropriate resources for checking and ensuring flavouring compliance at the various stages of production:

- Checking the compliance of the raw materials by verifying the supplier documentation;
- On reception of CDS and/or NCS: checking for compliance with specifications by documentary and/or analytical verification (the nature and frequency of analytical checks are defined in the risk management plan);
- Regulatory compliance of the flavouring formulation at the time of creation, followed by compliance with that formulation during production (verifiable by traceability).



1.3. Checking the compliance of natural status flavourings: role of analytical controls

Checking the compliance of natural status flavourings is based on the naturalness of the flavouring components (CDS and/or NCS), which depends on several criteria:

- The nature of the source materials
- The processes used to obtain the materials

- The authenticity or identification in nature in the case of CDS

Therefore, checking the compliance of natural status flavourings is a multi-criteria process; one of these criteria can be supported by analytical expertise.

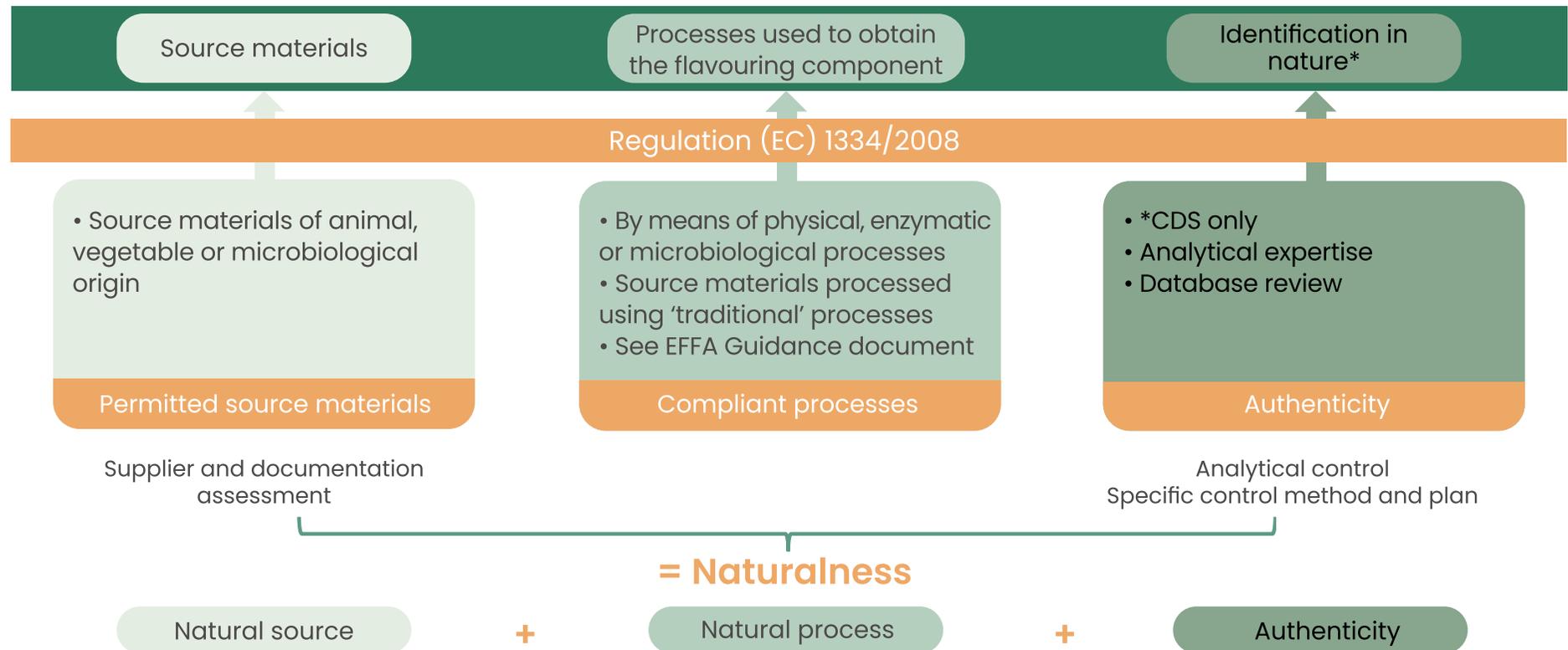


Figure 1: Criteria governing the compliance of natural flavouring components (CDS and NCS)



As a result, checking the compliance of natural status flavourings is largely based on checking raw material documentation: supplier guarantees and production process control. The checking of documentation and analytical control complement each other in ensuring compliance of raw materials (RM), and therefore of natural status flavourings.

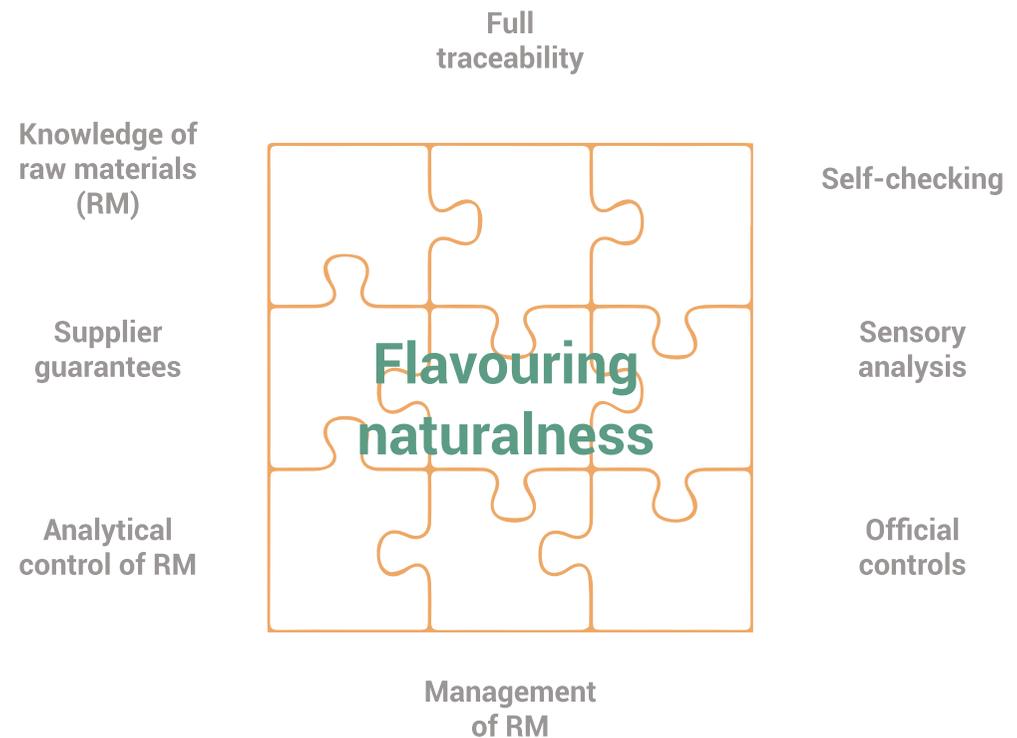


Figure 2: Criteria governing the compliance of natural status flavourings

- **Controls applied to aromatic raw materials (CDS and NCS)**

> For CDS, the EFFA (European Flavour Association) Guidance Document on Natural Processes¹ reviews the various analytical methods available for use by the flavouring industry. These can be used to assess the compliance of the processes used to manufacture a flavouring claimed to be of natural status. EFFA stresses that the analytical approach to the naturalness of CDS has its limits, and that interpretation is rarely unequivocal.

For example, chiral analysis (and particularly measuring the enantiomeric ratio of a chiral substance) or carbon-14 analysis can provide clues regarding the naturalness of the substance in question (see dedicated Focus).

> For NCS, the complex and variable nature of their composition makes interpretation rather challenging. Attempts have been made to characterise some NCS, but many parameters can modify their composition, not only those of the source material (seasonality, species, growing conditions, etc.), but also those of the processes used to obtain the NCS.

- **Controls applied to formulated flavourings and flavoured foods**

Both formulated flavourings and flavoured foods are complex blends that may contain hundreds of different molecules.

Analytical control of formulated flavourings or flavoured foods is therefore a very complex process, due to matrix effects, issues around the sensitivity of the methods used (the quantities of product to be analysed are often very small, etc.), issues around sample preparation, etc.

For formulated flavourings or flavoured foods, the analytical approach can be used to assess either the naturalness of the manufacturing processes or the authenticity of the flavouring source material (see part 2).

In addition to this direct approach to the control of the conformity of natural flavouring components, assessment can sometimes include searching for molecules not identified in nature or synthetic markers directly in the food product.

Careful examination is essential when interpreting the results in order to take full account of the characteristics of the flavoured food and the whole production process.

- **The responsibilities of operators in terms of compliance control**

> In most cases, flavouring manufacturers apply analytical controls to establish the authenticity of raw materials, rather than of formulated flavourings. This use of analytical controls is not systematic and is based on the flavouring manufacturer's own risk analysis of these raw materials.

Flavouring manufacturers apply analytical controls to formulated flavourings only rarely, and often in response to requests from customers (although the analytical results obtained are not always relevant).

> In most cases, external laboratories apply analytical controls to formulated flavourings or flavoured foods, although this does not rule out requests for controls to be applied to aromatic raw materials.

¹ For more details, see <https://effa.eu/library/guidance-documents>

2. Assessing the compliance of a sales description that may refer to the name of a flavouring source material

2.1. Regulatory aspects

Article 16 of Regulation (EC) 1334/2008 sets out the conditions for using the term 'natural' in a sales description; recital 26 provides additional information (see below).

There are four possible sales descriptions that can be used for natural status flavourings, but in practice, only the following three are commonly used. These three descriptions are mutually exclusive.

- **'Natural X flavouring'**, where X is the source material of the flavouring concerned: Defined in Article 16.4

4. 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 has been obtained exclusively or by at least 95% by w/w from the source material referred to.

- **'Natural X flavouring with other natural flavourings'**: Defined in Article 16.5

5. The term '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 easily be recognised.

- **'Natural flavouring'**: Defined in Article 16.6

6. The term 'natural flavouring' may only be used if the flavouring component is derived from different source materials and where a reference to the source materials would not reflect their flavour or taste

Recital 26 (reproduced below) clarifies the requirements of the Regulation regarding the use of the term 'natural' in the description of a flavouring. This recital also introduces sensory criteria relating to the source of the flavouring, through the concepts of organoleptic 'note' and 'recognisable...flavour'.

(26) 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.

EFFA has developed a guidance document explaining the provisions of Regulation (EC) 1334/2008 and their interpretation by the flavouring industry. This document is publicly available from their website: [EFFA Guidance Document on the EC Regulation on Flavourings](#).



2.2. Ensuring the compliance of flavourings whose description may include the name of a flavouring source material

The general considerations applying to natural status flavourings remain valid (see 1.2);

In accordance with these requirements, the following criteria must also be verified:

- For 'natural X flavourings', the formulation must comply with the weight criteria set out in Art. 16.4. (95% w/w minimum). (Figures 3 & 4)

> N.B.: The '95% w/w' ratio calculation is based on the total weight of flavouring components used in the formulation of the flavouring part. In accordance with good manufacturing practice, extraction solvents are eliminated in whole or in part, and are therefore an integral component of the flavouring preparation. Conversely, solvents used as carriers to dissolve, dilute or disperse after the extraction of NCS in compliance with Regulation (EC) 1334/2008 are not included in the calculation.

In their opinion of 31 January 2013, the experts of the SCoFAH² confirmed that [in determining the ratio of flavouring components derived or not from the source referred (so-called 95/5)] "the total amount of NCS and CDS should be calculated; NCS should be taken into account in their entirety for this purpose".

Annexes of the EFFA Guidance Document also include detailed explanations of the wording to be considered as not misleading within the meaning of Recital 26.

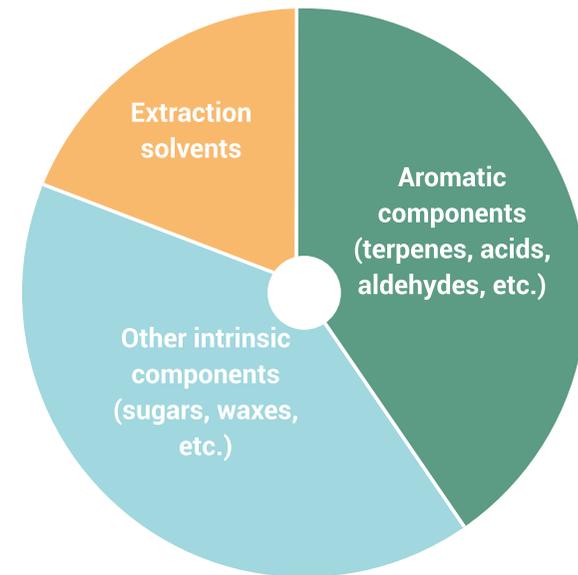


Figure 3: Composition of a flavouring preparation

²SCoFAH: The Standing Committee on the Food Chain and Animal Health, now known as SCOPAFF: The Standing Committee on Plants, Animals, Food and Feed

- **Sensory analysis by a trained panel to verify, where necessary, the sensory impact at the recommended doses in a model environment or in the intended application.**

> For 'natural X flavourings', EFFA has developed a tool named the Flavour Wheel to indicate whether or not such a flavouring complies with the Regulation (see: EFFA Guidance Document).

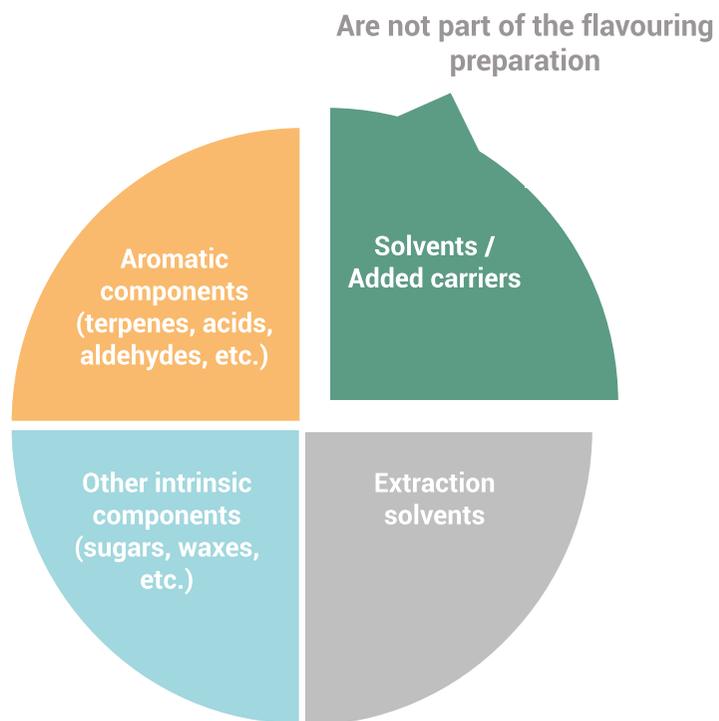


Figure 4: 95/5 calculation for a 'natural X flavouring'
(Article 16.4 of the Flavouring Regulation)

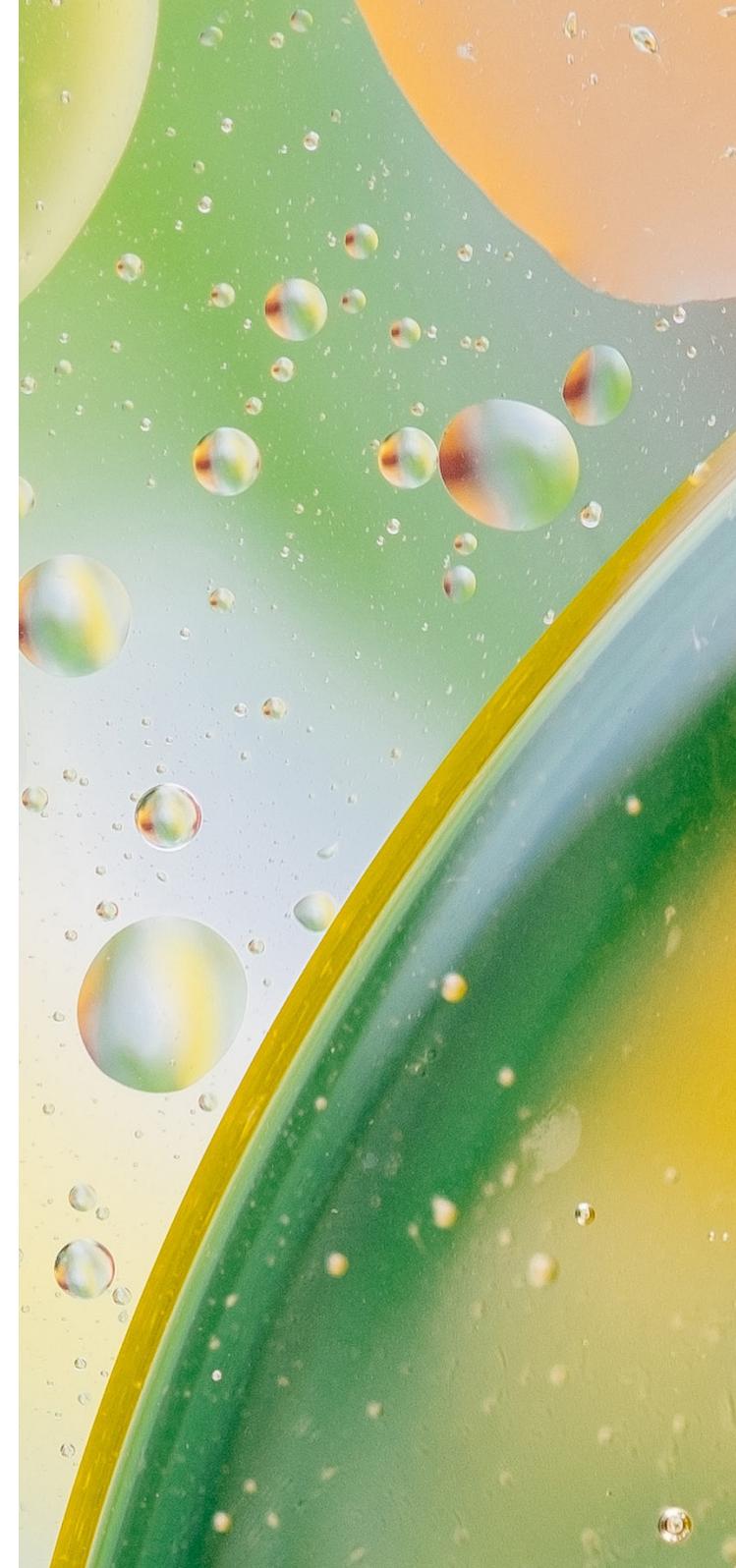


2.3. Checking the compliance of a sales description ‘natural X flavouring’: role of analytical controls

The majority of ‘natural X flavouring’ analyses are mostly conducted at the request of customers.

To the best of our knowledge, there is no prescriptive or universal analytical approach to assessing the compliance of flavourings, as referred to in Articles 16.4, 16.5 and 16.6 of the Flavouring Regulation.

- **For ‘Natural ‘X’ flavourings:** Some methods are available for assessing the authenticity of the source material (X) used in these flavourings. However, interpretation of the results must take into account the complexity of such formulated flavourings (presence of multiple flavouring components from the same source, etc.). It would therefore be more appropriate to check the authenticity of the source material (X) for each flavouring component, particularly NCS.



3. Conclusion

In conclusion, checking the regulatory compliance of natural status flavourings is a multifactorial process. The analytical approach allows to gather clues regarding the naturalness or otherwise of a flavouring. Analytical results alone are not sufficient to reach a conclusion; they should be supplemented by examination of other criteria, including verification of the formulation, validation of manufacturing processes, results of sensory analysis, etc.

A number of Focus documents are currently in preparation covering the most commonly used analytical methods; these documents will set out the benefits and limitations of these methods when used for checking the regulatory compliance of natural status flavourings.

Thus, a set of results from different analysis protocols may ultimately evidence the naturalness or authentic nature of a flavouring. Nevertheless, they should be accompanied by an assessment of the guarantees of compliance provided by the producer of the flavouring in terms of processes, formulation, etc.

The profession is committed to protecting the intellectual property of its formulations, and therefore only the authorities official control has access to them.

EFFA has issued a Position Paper on this subject: [EFFA Position Paper on Intellectual Property \(IP\) and Trade Secrets](#)

Bibliographie

- [Regulation \(CE\) 1334/2008 'Flavouring'](#)
- [Regulation \(CE\) 178/2002 'General Food Law'](#)
- [EFFA Guidance Document on the EC Regulation on Flavourings](#)
- [EFFA Guidance Document for the Production of Natural Flavouring Substances and \(Natural\) Flavouring Preparations in the EU](#)

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