



Short Guide

Question YES/NO Conditions/notes

May I use ORGANIC natural flavourings in my ORGANIC production?



Absolutely yes

May I produce ORGANIC natural flavourings?



Yes, provided that the source material is ORGANIC and that any additives are authorized in ORGANIC production. The reference to the source material must always be declared

May I use a NON ORGANIC "natural lemon flavouring" in my ORGANIC production?



Yes, after making sure that the flavouring does not contain GMOs and/or nanomaterials and ionising radiation was not used. Remember that flavourings are considered agricultural products and that the minimum of 95% organic agricultural ingredients rule needs to be respected

May I use a NON ORGANIC "natural vanilla flavouring" in my ORGANIC production whose technical sheet highlights the use of additives that are not allowed in organic production?



Yes, provided that the additive serves no technological function in the finished product (carry over principle)

May I use ORGANIC lemon juice and NON ORGANIC natural lemon flavouring (limonene) in my ORGANIC production?



Yes: an organic ingredient cannot be present together with the same ingredient in non-organic form, but in this case the two ingredients are not the same: limonene is a defined chemical substance isolated from the natural source lemon, but different from it

May I use a NON ORGANIC simple "natural flavouring", without mentioning the source material in my ORGANIC production?



No, the reference to the source material must always be declared

May I use a NON ORGANIC "natural peppermint flavouring with other natural flavourings" in my ORGANIC production?

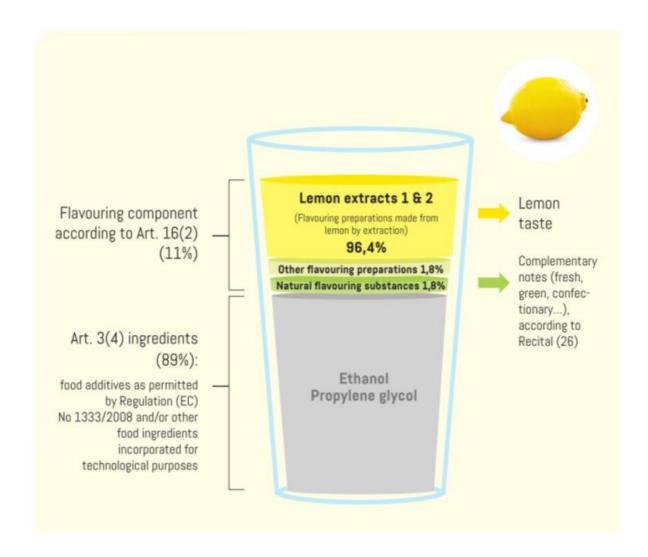


No, this category of flavouring is not authorized

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Recommendation: read a more in-depth review on the following pages. In case you have any doubts, consult your control body or authority

Schematic Presentation of the Flavouring



The above schematic presentation is taken from *EFFA Guidance Document on the new EU Organic Regulation in relation to flavourings*¹

¹ <u>EFFA Guidance Document</u> on the new EU Organic Regulation in relation to flavourings of 19 Feb. 2021

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1 Introduction

This guidance is based on IFOAM Organics Europe understanding of the new Regulation (EU) 2018/848 (referred to in this document as the Organic Regulation) and it provides an overview of the changing legal situation as of 1 January 2022.

The following questions are answered in this guidance:

- Which flavourings can organic food processors use from 1 January 2022?
- What information do they need to ensure that they are legally compliant?

For this purpose, a checklist and a template for a declaration of compliance with the ban on genetically modified organisms (GMOs) according to the Organic Regulation are included in the Annex I and II of this Guidance.

2 In brief - an overview of the most important requirements for the use of conventional flavourings

Flavourings are mentioned in 3 points of the Organic Regulation:

- 1. Article 16: production rules for processed food
- 2. Chapter 4: labelling => rules for organic flavourings
- 3. Annex II Part IV: Processed food, production rules

According to the new Organic Regulation, only:

- a) natural flavourings that are derived in the flavouring part to at least 95 %by weight from the namegiving source material (food, food category, of plant or animal origin)
 and/or
- b) Flavouring preparations from foodstuffs

can be used.

It should also be noted that

- c) flavourings in organic food are counted as agricultural ingredients for the purposes of calculation and quantity restriction (see chapter 6.1)
- d) conventional flavourings can only be used in organic food up to a proportion of 5% by weight (see chapter 6.2).

Conventional flavourings may be used if

- e) they as well as their components do not contain genetically modified organisms (GMOs) and have not been produced from or by a GMO (see chapter 7.1)
- f) do not contain nanomaterials (see chapter 7.2)
- g) have not been treated with ionizing radiation (see Chapter 7.3).

3 Legal requirements: Organic Regulation (EU) 2018/848 & Flavouring Regulation (EC) No 1334/2008

3.1 Use of conventional flavourings in organic foods

Organic foods consist of organic ingredients. Conventional ingredients can only be used under certain conditions. Conventional ingredients need to be explicitly authorized at EU level or temporarily at National level before they can be used in organic food up to a maximum of 5%. Conventional flavourings fall under the same rule. This guidance clarifies in detail which conventional flavourings may be used in organic food and to what extent.

3.2 What does the Organic Regulation say?

The new Organic Regulation defines the rules for the production of processed organic food under Annex II, Part IV, which also includes the use of flavourings in organic food.

Under Annex II, Part IV, point 2.2 "Use of certain products and substances in the processing of food", reference is made to the detailed requirements for the use of flavourings. Thus, under point 2.2.2 b) there is a reference to the substances and products which may be used as flavourings for the processing of organic foods. For the use of flavourings, reference is made to Article 3(2)(c) and (d)(i) and Article 16(2), (3) and (4) of Regulation (EC) No 1334/2008 (referred to in this document as the Flavouring Regulation).

Organic Regulation (EU) 2018/848

Annex II, Part IV: Processed food production rules

2. Detailed requirements for the production of processed food

2.2.1. ...

2.2.2 In the processing of food, the following products and substances may be used:

(a) ...

(b) substances and products defined in points (c) and (d)(i) of Article 3(2) of Regulation (EC) No 1334/2008 that have been labelled as natural flavouring substances or natural flavouring preparations in accordance with Article 16(2), (3) and (4) of that Regulation;

Additionally, article 60 of the Organic Regulation is about *Transitional measures for stocks of organic products* produced in accordance with Regulation (EC) No 834/2007: Products produced in accordance with Regulation (EC) No 834/2007 before 1 January 2022 may be placed on the market after that date until stocks are exhausted.

For flavourings this means that:

- a generic "organic natural flavouring" or a "organic natural flavouring of X with other natural flavourings" certified organic according to regulation (EC) No.834/2007 before 1 January 2022 may be placed on the market until the stocks are exhausted, but cannot be used as an ingredient of an organic product. This is the interpretation in some Member States, please check with your Control Body/Authority to have it confirmed.
- products made with some "generic natural flavouring" before 1 January 2022 already in the market or already in stock can be sold, as they were compliant with the legislation in force at the time of production.

Products made after 1 January 2022 must comply with the new legislation: flavourings may only be "natural X flavouring" (more specific declaration options such as "X preparation" are also possible) or "organic X natural flavouring".

- Flavouring preparations may only be produced from foodstuffs, whereby the extended definition of foodstuffs according to the Flavouring Regulation is applicable here. Source materials are considered to be food if they can be proven to have been used for the production of flavourings before 20 January 2011.

3.3 What does the Flavouring Regulation say?

Article 16 of the Flavouring Regulation, paragraphs (2) to (6) define the labelling of various natural flavourings. However, the Organic Regulation only allows the flavourings that meet the requirements of Article 16 (2), (3) and (4) of the Flavouring Regulation:

- Article 16 (2) defines the requirements for the use of the term "natural".
- Article 16 (3) defines the requirements for the use of the term "natural flavouring substance(s)".
- Article 16 (4) defines the labeling of natural flavourings derived from the named source material: in these flavourings, at least 95% by weight of the flavouring components are derived from the named source material. These are so-called natural X-flavourings. The X stands for the source material.

The other labelling options of natural flavourings in Article 16 (5) and (6) of the Flavouring Regulation are not permitted under the Organic Regulation.

How the linkage of Articles 16 (2), (3) and (4) is to be interpreted was unclear for a long time. However, the EU Commission stated in its letter² of 11 December 2018 that this should mean that only natural X-flavourings are permitted.

Flavouring Regulation (EC) No 1334/2008

Article 16: Specific requirements for the use of the term "natural".

- 1. ...
- 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.
- 3. The term 'natural flavouring substance(s)' may only be used for flavourings in which the flavouring component contains exclusively natural flavouring substances.
- 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.

The description shall read 'natural "food(s) or food category or source(s)" flavouring'.

- 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 mate-rial referred to, the flavour of which can easily be recognised.*
- 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*.
- * Not permitted as an organic ingredient in organic products

An operator who still had in stock generic "natural flavourings" purchased before 1 January 2022 cannot continue to use them in a product labelled as organic after that date.

There is an exception to this provision, and it is that represented by Third Countries recognised for the purpose of equivalence under Regulation (EC) No 834/2007, which continue to be recognised as such under Regulation (EU) 848/2018 for a limited period which ends by December 2026 at the latest. By December 2026 an international trade agreement will have to be concluded.

This exception refers to finished products from Third Countries, but does not extend to raw materials and semi-finished products intended to be subsequently processed or packaged in the EU.

By way of derogation, a fruit tea produced and packaged in Sri Lanka with a generic "natural flavouring" can continue to be provisionally qualified as organic until the new recognition (but no later than December 2026).

A mango puree produced in India with a generic "natural flavouring" cannot be used to produce a fruit yoghurt in the EU.

² https://effa.eu/library/guidance-documents

3.3.1 How are natural flavouring substances and flavouring preparations defined?

The origin of these natural flavouring substances and flavouring extracts and the manufacturing processes that may be used are specified in Article 3 (2) c) and d) i) of the flavouring regulation, to which the Organic Regulation also refers.

According to Article 3 (2) (b) of the Flavouring Regulation, flavouring substances are chemically defined substances with flavouring properties. Article 3 (2) (c) and (d) (i) of the Flavouring Regulation describe these natural flavouring substances and flavouring preparations in more detail:

- Letter (c) describes natural flavouring substances as substances which have been obtained only by
 physical, enzymatic or microbiological processes from plant, animal or microbiological source
 materials and which are used as such or prepared for human consumption by means of one or more
 of the conventional food preparation processes listed in Annex II. They occur naturally and are found
 in nature.
- Subparagraph (d)(i) allows flavouring extracts from food, including the expanded definition of food (see Chapter 2.4), if they are obtained by physical, enzymatic or microbiological processes and they are used as such or prepared for human consumption by one or more of the traditional food preparation processes listed in Annex II.
- Flavouring extracts referred to in point (d)(ii), namely those derived from substances which are not food, are not permitted.

Flavouring Regulation (EC) No 1334/2008

Article 3 Definitions

For the purposes of this Regulation, the following definitions shall also apply:

a) ...

b) ...

- c) 'natural flavouring substance' shall mean a flavouring substance obtained by appropriate physical, enzymatic or micro-biological 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*

*Not permitted as an organic ingredient in organic products

3.3.2 Expanded definition of food for flavouring preparations

As described, only flavouring preparations from food may be used in organic products, i.e., no flavouring preparations from other substances. Foods, according to the Basic Food Regulation (EC) No 178/2002 Article 2, are "substances or products intended to be, or reasonably expected to be ingested by humans in a processed, partially processed or unprocessed state."

However, the Flavouring Regulation allows for an expansion of the definition of food. All source materials are considered food for which there is significant evidence of use in the production of flavourings to date (effective date 20 January 2011, date of application of the Flavouring Regulation).

Therefore, if the flavouring producer can prove that the starting material was already used for the production of flavouring preparations before the cut-off date of 20 January 2011, this starting material is considered a food. This may involve substances such as rosewood or strawberry leaves. Currently, no flavouring preparations from non-foods are approved in the EU (as of February 2021).

Flavouring Regulation (EC) No 1334/2008

Article 3 Definitions

3. For the purpose of the definitions listed in paragraph 2(d), (e), (g) and (j), source materials for which hitherto there is significant evidence of use for the production of flavourings shall be considered as food for the purpose of this Regulation.

4 Composition of conventional flavourings

Conventional flavourings compliant to the Organic Regulation can be used directly. They do not have to meet any further approval requirements.

The approval of conventional flavourings according to Article 16 (4) of the Flavouring Regulation is directly applicable in the Organic Regulation.

4.1 Flavouring ingredient

The natural X-flavourings according to Article 16 (4) of the Flavouring Regulation must have at least 95% by weight of their flavouring component derived from the source material referred to.

In order to avoid misleading the consumer, the proportion of natural flavouring substances or flavouring extracts from other sources may not exceed 5% and may only be used for standardization or to give, for example, a fresher, sharper, more mature or greener flavouring (recital 26 of Regulation (EC) No 1334/2008). They must not enhance the flavouring note.

In Germany, the Working Group of Food Chemical Experts of the Federal States and the Federal Office of Consumer Protection and Food Safety (ALS) has also issued Resolution 2018/14³ on this subject. In this, it states that the flavour of the source material must be clearly recognizable in the food and that the flavour must not be predominantly determined by the 5% component. Rounding off the flavouring is thus permitted, but not enhancing or replicating the flavouring.

³ http://bvl.bund.de/SharedDocs/Downloads/01 Lebensmittel/ALS ALTS/ALS NEU/ALS Stellungnahmen 112 Sitzung 2018.pdf? blob=publicationFile&v=

4.1.1 Diverging views on the assessment of the flavouring component according to Article 16 (4) of the Flavouring Regulation

In Article 16 (4) of the Flavouring Regulation, the 95% by weight refers to the flavouring component. However, this term is not further defined in the Flavouring Regulation. This leads to different interpretations as far as the crediting of flavouring preparations is concerned. This is because flavouring preparations are very complex. It is now a question of whether flavouring preparations can be credited as a whole or whether only the flavour-active components contained in the flavouring preparation can be credited.

There are different views at EU and national level in detail on the interpretation of Article 16 (4)4:

- EU level: the EU Commission, via the Standing Committee on Food Chain and Animal Health (SCoFCAH), in its note of 22 January13 (see References at the end of this guidance), expresses the opinion that complex flavouring preparations in their entirety/as a whole from the source material referred to count towards the 95% by weight.
- In Germany the Working Group of Food Chemical Experts of the Federal States and the Federal Office
 of Consumer Protection and Food Safety (ALS) comes to the opinion, based on its decision 2012/29⁵,
 that only the flavouring components of the flavouring extract count towards the 95% of the weight,
 but not the entire components of the flavouring extract.

4.2 Non-flavouring ingredient

Flavourings may contain approved food additives and/or other food ingredients for technological purposes, such as carriers. These are used, for example, for their storage, standardization, dilution or solution and stabilization. They may not have a technological effect in organic foods themselves and consequently are not included in the labelling on the final product.

Legal basis:

All additives authorized under the Food Additives Regulation (EC) No. 1333/2008 Article 4 (2) in the Community list of additives in Annex III, Part 4 under "Food additives including carriers in food flavourings" are approved and may be used for conventional flavourings used in an organic product.

Food Additives Regulation (EC) 1333/2008, Annex I

•••

(5) 'carriers' are substances used to dissolve, dilute, disperse or otherwise physically modify a food additive or a flavouring, food enzyme, nutrient and/or other substance added for nutritional or physiological purposes to a food without altering its function (and without exerting any technological effect themselves) in order to facilitate its handling, application or use;

There is no labelling requirement for additives used in a flavouring in the list of ingredients of the processed product, provided that they do not have a technological role in the finished product.

The Organic Regulation does not impose any restrictions on non-flavouring ingredients for conventional flavourings in organic foods, as long as they have a technological effect only in the flavouring and no effect in the organic finished product. All additives permitted and used according to the Flavouring Regulation (for example, propylene glycol or triacetin) or other ingredients for technological purposes (for example, food ingredients such as maltodextrin/vegetable oils used as carriers) are permitted, without any obligation to name them on the labels of the finished product.

⁴ http://aromenverband.de/fachthemen/stellungnahmen/positionspapier-artikel-16 4/

http://bvl.bund.de/SharedDocs/Downloads/01 Lebensmittel/ALS ALTS/ALS Stellungnahmen 100 Sitzung 2012.pdf? blob=publicationFile

However, it should be reiterated that the additives used in a flavouring must comply with the conditions set out in Regulation (EC) 1333/2008 on additives, which provide for thresholds (or "quantum satis").

In other words, there is no impediment to the use of sodium benzoate as a preservative for a flavouring, but the quantity must be that strictly necessary for this technological function, excluding that it can act as a preservative for the product to which the flavouring is added.

If one or more additives used in a flavouring have an impact on the finished product, they must be included in the list of authorised food additives in organic production (Article 24 (2)(a) of Regulation (EU) No. 2018/848) and they must be listed in the ingredient list in the label of the processed product.

It should be borne in mind that, since the natural flavouring of X is considered an ingredient of agricultural origin, it must also be included in the calculation of the percentage of ingredients of agricultural origin for the purpose of indicating their origin (EU Agriculture, non-EU Agriculture, EU/non-EU Agriculture, name of a country or a region).

It means that processors need information on the origin of the agricultural ingredients of the natural flavouring through the product specification/technical sheet of the natural flavouring or through a separate declaration of the supplier.

5 Labelling of Flavourings

5.1 Labeling of Flavourings to the Food Processor

The requirements of Article 14 of the Flavouring Regulation apply to the labelling of flavourings not intended for the final consumer: the flavourings may only be marketed with the information specified in Article 15. This information must be indicated visibly, clearly legibly and indelibly on packaging or containers and/or on the specification. This includes the indication of the sales description, which shall be indicated by a more precise indication or description of the flavouring (e.g. natural strawberry flavouring).

5.2 Labeling of Flavourings to the End Consumer

Towards the final consumer, flavourings are labeled according to the Food Information Regulation (EU) No 1169/2011 Annex VII Part D.

Natural X-flavourings may be indicated on the final product.

Regulation (EU) No 1169/2011 Annex VII

Part D - DESIGNATION OF FLAVOURINGS IN THE LIST OF INGREDIENTS

- 1. Flavourings shall be designated either by the terms:
- 'flavouring(s)' or by a more specific name or description of the flavouring if the flavouring component contains flavourings as defined in points (b), (c), (d), (e), (f), (g) and (h) of Article 3(2) of Regulation (EC) No 1334/2008,
- 2. The term 'natural' for the description of flavourings shall be used in accordance with Article 16 of Regulation (EC) No 1334/2008.

Note

- For the labelling of flavourings not intended for the final consumer, the information referred to in Article 15 shall appear on the packaging or container of the product concerned and/or in the accompanying documents.
- In the flavouring designation on the final product, either the name of the food or food category referred to or the plant or animal source material may be designated for a natural X flavouring.

Examples of flavouring designations to the end user:

- Flavourings from foods, plant or animal origin: natural pepper flavouring, natural lemon flavouring, natural beef flavouring, strawberry extract.
- Flavourings from food categories: natural cheese flavouring, natural spice flavouring, natural citrus flavouring, natural herbs de Provence flavouring
- According to Regulation (EC) No 1334/2008, art.15, the sale description to be used in the ingredients list is either the word "natural flavouring" or a more specific name or description of the flavouring. For instance, the following description are compliant: "essential oil of XXX", "extract of XXX", "concentrated juice of XXX", "infusion of XXX", etc.

6 Calculation and quantity restriction of flavourings in organic foods

Conventional flavourings used in organic foods are co-determinants in the quantity calculation of whether an organic food consists predominantly of ingredients of agricultural origin. They can only be used in limited quantities.

6.1 Flavourings as ingredients of agricultural origin

In organic foodstuffs, with the entry into force of the Organic Regulation (EU) 2018/848, flavourings count as ingredients of agricultural origin for the purpose of quantity calculation.

The Organic Regulation lists in Annex II, Part IV 2.2.4 b) which preparations and substances are not counted as ingredients of agricultural origin. Flavourings are not listed here. They are named in Annex II, Part IV 2.2.2 b). This means that they must be counted as ingredients of agricultural origin.

Regulation (EU) 2018/848, Annex II, Part IV

2.2.4 For the purpose of the calculation referred to in Article 30(5), the following rules shall apply:

(a) ...

(b) preparations and substances referred to in points (a), (c), (d), (e) and (f) of point 2.2.2 shall not be calculated as agricultural ingredients;

Organic foods must in principle be produced predominantly (more than 50%) from ingredients of agricultural origin in order to be labeled with reference to organic, in accordance with Annex II, Part IV 2.1 a). Water and salt are not included in the calculation.

Regulation (EU) 2018/848, Annex II, Part IV

- 2. detailed requirements for the production of processed foods
- 2.1 The following conditions shall apply to the composition of processed organic food:
- (a) the product shall be produced mainly from agricultural ingredients or products intended for use as food listed in Annex I; for the purpose of determining whether a product has been produced mainly from those products, added water and salt shall not be taken into account

6.2 Quantitative Limitation of Conventional Flavourings

In foods labeled as organic, at least 95% of the ingredients of agricultural origin must be organically produced. In an organic food, conventional flavourings as ingredients of agricultural origin can be part of the maximum 5% and they must be included in the calculation for organic food labeling.

6.3 Examples of calculation and quantity restriction

Example 1: Organic herb salt

Ingredients: salt (80%), herbs* (19%), natural herbs de Provence flavouring (1%); *from organic farming.

The organic herbal salt consists of salt, organic herbs and a flavouring. For the calculation of quantities, the salt is not calculated. The herbs and flavouring are ingredients of agricultural origin and must be included for the calculation. Therefore, because salt is not counted, the product consists of 100% ingredients of agricultural origin. The rule that the product must contain at least 50% ingredients of agricultural origin is therefore met. For the calculation, note that the organic food must contain ingredients that are at least 95% organic, and up to 5% conventional ingredients may be added to the food. Herbs can only be used in organic quality, because herbs from conventional production are not allowed in organic products. In terms of ingredients of agricultural origin, the herbs in this example account for 95%. The remaining 5% of these ingredients may consist of conventional flavouring.

Example 2: organic raspberry yogurt.

Ingredients: Yogurt*, sugar*, raspberry puree* (4%), raspberry juice from raspberry juice concentrate* (4%), natural raspberry flavouring (3%).

*Ingredients from organic farming

This yogurt may be labeled as organic raspberry yogurt because it is made primarily from ingredients of agricultural origin and less than 5% of the ingredients of agricultural origin are from conventional production.

Example 3: organic vital water with ginseng flavour.

Ingredients: Water, natural ginseng flavouring* *Ingredients from organic farming.

This near-water drink consists only of water and natural flavouring. The natural flavouring is an ingredient of agricultural origin. Therefore, because water is not counted, the product consists of 100% ingredients of agricultural origin. The rule that the product must contain at least 50% ingredients of agricultural origin is therefore met.

In addition, at least 95% of the agricultural ingredients must come from organic farming. Since the natural ginseng flavouring is the only agricultural ingredient, it must be at least 95% organic ginseng extract to declare the near-water beverage as an organic food. The remaining 5% can be conventional natural flavouring and/or flavouring extracts.

However, due to the additional rules of the flavouring regulation for "natural X-flavourings," these 5% conventional natural flavouring substances and/or flavouring extracts may only serve to standardize or give a special note.

Example 4: raspberry flavoured yogurt.

Ingredients: Yogurt*, sugar*, natural raspberry flavouring (6%). *Ingredients from organic farming

This yogurt, although made from organic milk and consisting mainly of ingredients of agricultural origin, may not be labeled as an organic product because it contains more than 5% conventional ingredients of agricultural origin.

If more than 5% conventional ingredients are used, the food loses its status as an organic product in the sales description (95% organic; Article 30 (5) a) of the Organic Regulation).

It may be declared as a product according to Article 30 (5) b) of the Regulation on Organic Products exclusively in the list of ingredients with organic ingredients, provided that the specific requirements of the Regulation on Organic Products are met for this purpose.

6.4 Use of the same organic and conventional ingredients in a product

It should further be noted that an organic ingredient may not occur together with the same conventional ingredient in the product (Annex II, Part IV 2.1. (b) of the Organic Regulation). According to the Food Information Regulation (EU) No 1169/2011 Article 2 (f), ingredients are any substance or product that is used in the production process and remains present in the finished product. This also includes flavourings.

Organic Regulation (EU) 2018/848, Annex II, Part IV

- 2. detailed requirements for the production of processed foods
- 2.1 The following shall apply to the composition of processed organic food:

...

(b) an organic ingredient shall not be present together with the same ingredient in non-organic form

On this issue there are some articulate/divergent opinions among the Commission and some Member state. IFOAM Organics Europe recommends that you refer to your control body in case of doubt.

For information purposes only, we report the position of the Commission about the notion of "same ingredients" in organic production.

Мау	Be used together with	
Natural flavouring substance obtained from rosemary (a defined chemical substance, not E 392)	Natural flavouring preparation of rosemary (obtained from dried leaves of rosemary)	YES, unless differentially designated and when the simultaneous used of these products is justified to obtain specific food characteristic
Natural flavouring preparation obtained from thyme (essential oil, containing thymol (20 to 54 %), myrcene, borneol, and linalool	Natural flavouring substance obtained from thyme (thymol only) FL No. 04.006 (BE)	YES, unless differentially designated and when the simultaneous used of these products is justified to obtain specific food characteristic

For information purposes only, we report that the European Flavour and Fragrance Association (EFFA) also provides information on non-concomitance in its Guidance Document⁶ on the new Organic Regulation in Annex IV (from page 14). It emphasizes that flavourings can differ in their specific composition in each case and therefore different lemon flavourings cannot per se be considered the same ingredient, as the composition of the flavouring component can vary considerably. EFFA argues that in the Organic Regulation, the legal requirements of distinctness do not refer to the source material, but to the ingredient itself.

⁶ https://effa.eu/library/guidance-documents

Example 1: Organic lemon pudding

Corn starch*, natural lemon flavouring (here: lemon oil)*, natural lemon flavouring (here: citral), salt *Ingredient from organic farming.

In these indications (without reference in brackets), no distinguishability of the ingredient natural lemon flavouring is recognizable. From a strictly technical point of view, lemon oil and citral are different defined chemical substances with flavouring properties, therefore there is no simultaneous presence of the same ingredient but given that some Member States have a different opinion on the issue and, consequently, the indications may lead to queries or complaints, it is advisable to check with your control body. Anyway, it would also be possible to declare natural lemon flavouring as a single ingredient, either as a conventional flavouring or, if the requirements are met, as an organic flavouring.

Example 2: organic lemon pudding

Corn starch*, lemon extract*, natural lemon flavouring, salt *Organic ingredient.

As in the previous case, there is a need for interpretation in these claims as to what extent the lemon extract and natural lemon flavouring should be considered the same ingredient. Until a common uncontested interpretation is established, in case of doubt it is advisable to check with your control body.

7 Exclusion of genetically modified organisms, nanomaterials and irradiation

7.1 Genetically modified organisms

According to Article 11 of the Organic Regulation, it is not allowed to use genetically modified organisms (GMOs), products produced from GMOs or products produced by GMOs in organic products.

Organic Regulation (EU) 2018/848, Article 11 - Prohibition of the use of GMOs.

- 1. GMOs, products produced from GMOs, and products produced by GMOs shall not be used in food or feed, or as food, feed, processing aids, plant protection products, fertilisers, soil conditioners, plant reproductive material, micro-organisms or animals in organic production.
- 2. For the purposes of the prohibition laid down in paragraph 1, with regard to GMOs and products produced from GMOs for food and feed, operators may rely on the labels of a product that have been affixed or provided pursuant to Directive 2001/18/EC, Regulation (EC) No 1829/2003 of the European Parliament and the Council or Regulation (EC) No 1830/2003 of the European Parliament and of the Council or any accompanying document provided pursuant thereto.
- 3. Operators may assume that no GMOs and no products produced from GMOS have been used in the manufacture of purchased food and feed where such products do not have a label affixed or provided, or are not accompanied by a document provided, pursuant to the legal acts referred to in paragraph 2, unless they have obtained other information indicating that the labelling of the products concerned is not in conformity with those legal acts.
- 4. For the purposes of the prohibition laid down in paragraph 1, with the regard to products not covered by paragraphs 2 and 3, operators using non-organic products purchased from third parties shall require the vendor to confirm that those products are not produced from GMOs or produced by GMOs.

Substances that are themselves GMOs or have been produced from them must be labeled accordingly in accordance with Article 4 B (6) of the Traceability and Labeling Regulation (EC) No. 1830/2003. This information must be provided for traceability at all stages of the commodity chain. Therefore, for these products, companies

can rely on the labels or on accompanying documents of the supplier. For substances derived from GMOs that are not covered by Regulation (EC) 1830/2003, such as processing aids, a GMO ban declaration is required.

Regulation (EC) No 1830/2003, Article 4

Traceability and labelling requirements for products consisting of or containing GMOs

A. TRACEABILITY

- 1. At the first stage of the placing on the market of a product consisting of or containing GMOs, including bulk quantities, operators shall ensure that the following information is transmitted in writing to the operator receiving the product:
- (a) that it contains or consists of GMOs;
- (b) the unique identifier(s) assigned to those GMOs in accordance with Article 8.
- 2. At all subsequent stages of the placing on the market of products referred to in paragraph 1, operators shall ensure that the information received in accordance with paragraph 1 is transmitted in writing to the operators receiving the products.

(3)... (4)... (5)...

B. LABELING

- 6. For products consisting of or containing GMOs, operators shall ensure that:
- (a) for pre-packaged products consisting of, or containing GMOs, the words 'This product contains genetically modified organisms' or 'This product contains genetically modified [name of organism(s)]' appear on a label;
- (b) for non-packaged products offered to the final consumer the words 'This product contains genetically modified organisms' or 'This product contains genetically modified [name of organism(s)]' shall appear on, or in connection with, the display of the product.

This paragraph shall be without prejudice or other specific requirements in Community legislation.

A GMO prohibition statement or equivalent confirmation is required for conventional ingredients.

Flavourings are composite products made up of several components: a flavouring component and a non-flavouring component. All components must not contain GMOs and must not have been produced from or by GMOs. The GMO prohibition declaration must refer to all components.

Further detailed information can be found in the "Interpretation of the ban on the use of genetic engineering in the production and processing of organic food"⁷.

For its part, the European Flavour and Fragrance Association (EFFA) provides information on the use/non-use of GMOs in its Guidance Document⁸ on the new Organic Regulation in Annex III (from page 9): "This prohibition applies not only on the final flavouring used in an organic food but also to every ingredient of the flavouring (flavouring components, and non-flavouring components i.e. additives, other food ingredients)".

⁷ https://www.aoel.org/wp-content/uploads/2019/04/Interpretation AoeL-BOELW-FiBL GVO-Verbot Bio-Lebensmittel.pdf

^{*} https://effa.eu/library/guidance-documents

Together with this correct statement, however, EFFA provides in its Questions and Answers:

"3. Is it possible to use maltodextrin manufactured with the help of enzymes produced by GMMs as carrier in an organic suitable flavouring?

Yes, under the condition that the maltodextrin is from conventional/non-GM source."

Given that Regulation (EC) No 1830/2003 on food and feed products produced from genetically modified organisms provides only the definitions of (a) products consisting of, or containing, GMOs,

and (b) food produced from GMOs, absolutely not considering a new category of food "produced with the help of GM enzymes" (which, in our opinion, falls completely into category b), you need to make sure that the data sheet clearly specifies that the flavouring does not consist, does not contain, is not produced from GMOs nor "with the help of GMOs".

Organic Regulation (EU) 2008/848, as the former organic regulation, consistently use the terms

"genetically modified organism/GMO", "produced from GMOs" and "produced by GMOs". Those terms are defined in Articles 3(58), 3(59), and 3(60) of Regulation (EU) 2018/848.

Even if not included in the Organic Regulation, a model declaration (or equivalent one) quite similar to that proposed in the Implementing Regulation (EC) No 889/2008 in Annex XIII is sufficient for this purpose. However, it is important to note that the signatories do not make any changes to the template, especially in the form of deletions.

Note

- For substances that are GMOs or produced from GMOs, the organic food producer can rely on the labeling, as these are subject to mandatory labeling.
- For substances produced from GMOs that do not require labeling or substances that may have been produced by GMOs, a GMO ban statement must be available.

7.2 Nanomaterials

According to Article 7 (e) of the Organic Regulation, foods containing or consisting of engineered nanomaterials must not be included in organic foods. Flavourings are foodstuffs according to the General Food Law Regulation (EC) No 178/2002. According to the Food Information Regulation (EU) No 1169/2011, ingredients in foodstuffs that are engineered nanomaterials must be clearly listed in the list of ingredients. Labelling is carried out on the label of the product. According to Article 1 (3), the Food Information Regulation applies to all stages of the food chain.

Regulation (EU) No 1169/2011

Article 18 List of ingredients

(1) ...

(3) All ingredients present in the form of engineered nano-materials shall be clearly indicated in the list of ingredients. The names of such ingredients shall be followed by the word 'nano' in brackets.

Note

- Organic food processors can rely on the fact that no engineered nanomaterials are present if they have not been explicitly labeled. The flavouring manufacturer informs the customer about the use of engineered nanomaterials in the flavouring via a note in the specification or in the documents accompanying the product.

7.3 Ionizing Radiation

According to Article 9 (4) of the Organic Regulation, organic foods or their source materials must not be treated with ionizing radiation. According to the Food Information Regulation (EU) No 1169/2011, foods treated with ionizing radiation must be labeled accordingly. A labeling is made on the label of the product. The Food Information Regulation Article 1 (3) applies at all stages of the food chain.

Regulation (EU) No 1169/2011 Annex VI, Part A

3. Foods treated with ionizing radiation shall bear one of the following indications:

'irradiated' or 'treated with ionising radiation' and other indications as stated in Directive 1999/2/EC of the European Parliament and of the Council of 22 February 1999 on the approximation of the laws of the Member States concerning foods and food ingredients treated with ionising radiation (1).

Note

- Organic food processors can be confident that no ionizing radiation has been used if it has not been explicitly labeled. The flavouring manufacturer informs the customers about the use of ionizing radiation in the manufacturing process of the flavouring via a note in the specification or in the documents accompanying the product.

8 Documents accompanying the product

8.1 Product accompanying documents

Since flavouring profiles for use in foods are often developed and produced in customized form, a flavouring made from its namesake source material, such as a natural strawberry flavouring, is not a standardized product. The documents accompanying the product must provide information on the compliance of the flavouring for the use in organic food.

According to Article 15 (1) of the Flavouring Regulation, the organic food processor receives all necessary information on the conformity of the flavouring on the packaging or in the accompanying documents.

Regulation (EC) No 1334/2008, Article 15

General requirements for the labelling of flavourings not intended for sale to the final consumer

(1) Where flavourings not intended for sale to the final consumer are offered for sale singly or mixed with other flavourings and/or with food ingredients and/or with the addition of other substances as referred to in Article 3(4), their packaging or containers shall bear the following information:

(a) Sales description: either the word "flavouring" or a more specific indication or description of the flavouring;

...

According to the Organic Regulation (Annex II Part IV 2.2.2 b), only flavourings that are labeled as natural flavouring substances or natural flavouring extracts according to Article 16 (2), (3) and (4) of Regulation (EC) No 1334/2008 may be used.

In combination with Article 16 (1), this means that the sales description according to Article 15 (1)(a) must be declared as "natural X flavouring" on the packaging or in the accompanying papers of the flavouring.

This allows the accompanying papers to sufficiently demonstrate that the designated flavouring is compliant with the Organic Regulation and may be used in organic foods (see checklist in the Annex I to this guidance).

9 Challenges in production

9.1 Production of conventional flavourings according to Art. 16 (4) of the Flavouring Regulation

The use of conventional flavourings according to Article 16 (4) of the Flavouring Regulation in organic food will lead to an increasing demand for source raw materials on the market. Rather low flavouring intensity in fruits (especially red and yellow fleshed fruits) poses an economic and ethical challenge (due to high raw material input) for flavouring producers and organic food processors.

9.2 Residues/contamination

During the production of natural flavouring substances or flavouring extracts, residues and contaminants that may be present in the starting material can be incorporated into the flavouring ingredient.

This may be particularly the case with starting materials obtained from the peel, as residues or contaminants are most likely to accumulate in this part. Although a general concentration of pesticides during the production of flavouring components cannot be assumed, this possibility must be taken into account.

As a rule, foods contain very low doses of flavourings, so that the input of residues of pesticides via flavourings is usually negligible. The regulations in EU pesticide and contaminant regulations must be observed and only suitable flavourings that comply with EU law may be used.

Restrictions regarding contaminants/residues that go beyond legal requirements can be secured by special agreements to minimize risks. Another alternative is the use of organic flavourings.

Organic flavourings

Article 30 5. (iii) in the case of flavourings, the terms "organic", derivatives and diminutives, such as 'bio' and 'eco', are only used for natural flavouring substances and natural flavouring preparations labelled in accordance with Article 16(2), (3) and (4) of Regulation (EC) No 1334/2008 and all of the flavouring components and carriers of flavouring components in the flavouring concerned are organic.

Other controversial issues

The competent authority of a EU Member State has raised the issue of "dual" flavourings (e.g. natural apple cinnamon flavouring) with the Commission, and are waiting for their response.

From a strictly technical point of view, a complex "natural forest fruit flavouring" or a "natural citrus flavouring" (but also a "natural mulled wine flavouring" and a "natural apple cinnamon flavouring") can be used in organic production, once that their flavouring component has been obtained by at least 95 % by w/w from the source material referred to, as pursuant to the Flavouring regulation they are "natural flavouring preparations", that is products, other than flavouring substances, obtained from food or food category.

But giving that there at the moment is no uniform procedure for counting the flavouring components in flavouring extracts in the EU or for "dual" flavourings, organic food processors must be aware of this inconsistency when sourcing natural X-flavourings from flavouring processors abroad and make sure that the flavourings comply with the provisions of their competent authority.

Then, once again, in case of doubt, refer to your control body.

10 References:

EU Regulations:

- Regulation (EU) 2018/848 on organic production and labeling of organic products. Consolidated on 01.01.2022
- Regulation (EC) No 1334/2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods. Consolidated on 21.11.2021
- Regulation (EC) No 1333/2008 on food additives. Consolidated on 22.02.2022
- Regulation (EU) No 1169/2011 on the provision of food information to consumers. Consolidated on 01.01.2018
- Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. Consolidated on 26.05.2021
- Regulation (EC) No 1829/2003 on genetically modified food and feed. Consolidated on 27.03.2021
- Regulation (EC) No 1830/2003 concerning traceability and labelling of genetically modified organisms and traceability of food and feed products produced from genetically modified organisms. Consolidated on 26.07.2019

Other documents:

- EFFA Guidance Document on the new EU Organic Regulation in relation to flavourings, 26 June 2019. EFFA Library
- <u>Statement</u> of the Working Group of Food Chemistry Experts of the German Federal States and the Federal Office of Consumer Protection and Food Safety (ALS), Statement No. 2018/14
- DVAI position paper on the interpretation of Article 16 (4)
- <u>Statement</u> of the Working Group of Food Chemistry Experts of the Federal States and the Federal Office of Consumer Protection and Food Safety (ALS), Statement 2012/29
- Interpretation of the ban on the use of genetic engineering in the production and processing of organic food, AöL, BÖLW, FiBL

Annex I

Possible checklist for the use of conventional flavourings in organic processing

	Legal Reference	Requirement	Question	Document	Check
1	Reg. (EC) No 1334/2008 Art. 16(4)	Composition of natural X flavouring or X extract	Is the specification "natural X flavouring" confirmed?	Specification (confirmation of classification/designation as "natural X flavouring") If applicable, additional confirmation of conformity with Decision 2012/29 of the ALS (only in Germany)	Yes/No Date Responsible
2	Reg. (EC) No 1334/2008 Recital 26		Has the remaining 5% of the flavouring ingredient been used only to standardize the flavouring?	Specification (confirmation of classification/designation as "natural X flavouring")	Yes/No Date Responsible
3	Reg. (EC) No 1334/2008 Art. 3(d) and 3(3)	Flavouring extract from food	Is the flavouring extract only obtained from a food (including the extended definition of food)9	Specification (confirmation of the designation as "natural X flavouring" according to Regulation (EC) No 1334/2008)	Yes/No Date Responsible
4	Reg. (EU) 848/2018 Art. 11	GMO prohibition	Have substances been used that are GMOs or have been produced from GMOs?	Product-accompanying document / specification	Yes/No Date Responsible
			Is there a GMO declaration for substances from or by GMOs?	Declaration from the supplier	Yes/No Date Responsible
5	Reg. (EU) 848/2018 Art. 7	Ban on engineered nanomaterials	Have engineered nanomaterials been used?	document / specification accompanying the product.	Yes/No Date Responsible
6	Reg. (EU) 848/2018 Art. 9	Prohibition of ionizing radiation	Has ionizing radiation been used in the aroma or in the starting materials?	product -accompanying document / specification	Yes/No Date Responsible

⁹ Currently, flavouring preparations from non-food sources are not authorised in the EU. As soon as flavouring preparations from non-food sources are authorised in the EU, it must be confirmed that they are not included.

Annex II

Possible template for a VENDOR DECLARATION ACCORDING TO ARTICLES 7, 9, 11(4) AND 32 OF REGULATION (EU) 848/2018

Name, address of vendor:							
Identification (e.g. lot or stock number): Product name:							
							Compone
(Specify a	(Specify all components existing in the product/used the last in the production process)						
For the p	ourpose of Article 7, 9 and 11 of Regulation	(EU) 2018/848 I declare that this product					
-	Was manufactured excluding any foodstuf	f containing manufactured nanomaterials or constituting such					
b) c) d)	b) Was manufactured excluding any use of ionizing radiation on the product and all its componentsc) Is not GMO, does not consist of GMO and have not been obtained "from" or "by" GMOs						
I do not h	nave any information which could suggest	that this statement is inaccurate.					
	eclare that the above named product comp on on the use of nanomaterials, ionizing ra	blies with Articles 7, 9 and 11 of Regulation (EU) $2018/848$ regarding the diation and GMOs.					
-	- · · · · · · · · · · · · · · · · · · ·	e where the agricultural raw materials of which the product is crials of which the product is composed have been farmed					
☐ In the	EU	☐ In a third Countries					
☐ Partly	in the EU and partly in a third Country	☐ In the following Country:					
	ke to inform our customer and its control be information comes to light which would ur	oody/authority immediately if this declaration is withdrawn or modified, ndermine its accuracy.					
custome	r to examine the accuracy of this declaration	s defined in Article 3 of Regulation (EU) 848/2018, which supervises our on and if necessary to take samples for analytic proof. I also accept that citution which has been appointed in writing by the control body.					
The unde	ersigned takes responsibility for the accura	cy of this declaration.					
Country,	place, date, signature of vendor:	Company stamp of vendor (if appropriate)					