

# EFFA Guidance Document on the new EU Organic Regulation in relation to flavourings

*This Guidance Document refers to the **Regulation (EU) 2018/848 on organic production and labelling of organic products** published on 14 June 2018 (“New EU Organic Regulation”). It is based on EFFA’s understanding of the “Organic Regulation” and additional clarification provided by the EU-Commission.<sup>1</sup> However this Guidance Document is subject to changes/modifications based on additional guidance which might be received from the EU-Commission.*

The “New EU Organic Regulation” provides certain provisions in relation to flavourings:

- The new Regulation offers two options with regard to the use of flavourings in organic foods: “organic suitable flavourings”<sup>2</sup> and “organic flavourings”<sup>2</sup>.
- Only flavourings, which are labelled according to Article 16(4) (natural <X> flavourings) of the Flavouring Regulation, may be used in the processing of organic food products.
- Flavourings used in organic foods are considered as a whole as agricultural ingredients and subsequently need to be taken into account as a whole for the “min 95% rule” applied to the final organic foods (i.e. at least 95% of the agricultural ingredients shall be organic).
- Given that flavourings are considered as processed foods, the “min 95% rule” also applies to the organic flavourings.<sup>2</sup>

## 1. Introduction

The “New EU Organic Regulation” (EU) 2018/848 was published on 14<sup>th</sup> June 2018 and entered into force on 17<sup>th</sup> June 2018.

This new framework Regulation has recently been amended by Regulation (EU) 2020/1693 and **will now apply on 1<sup>st</sup> January 2022** and it will repeal the Council Regulation (EC) No 834/2007. It contains modifications of the provisions regarding flavourings compared to Regulation (EC) No 834/2007 and introduces rules for organic flavourings.

The current paper expresses EFFA’s understanding of these provisions related to flavourings and their use in organic foods and is also based on additional clarification received from the EU-Commission.<sup>1</sup>

## 2. General Provisions

The authorisation for using flavourings in organic food is provided by point 2.2.2 (b) of Annex II part IV of the Regulation (EU) 2018/848 (hereinafter referred to as the “Organic Regulation”).

As pointed out by the Commission<sup>1</sup>: *“Point 2.2.2 provides a “direct” authorisation for the use of flavourings. Flavourings will not be authorised pursuant to Articles 24 and 25: no listing in annexes, no authorisation granted by member states. This overall authorisation does not impose that the flavourings have to be organic.”*

<sup>1</sup> For more information see letter from the EU-Commission (Mrs N. Sauze-Vandevyver, DG AGRI) from 04/03/2019 to EFFA-Secretariat.

<sup>2</sup> In this document the term “organic flavouring” shall be understood as flavourings that meet the requirements of the EU Organic Regulation Article 30 “use of the terms referring to organic production” – 5(a)(iii). Likewise, the term “organic suitable flavourings” refers to flavourings that meet the requirements according to Annex II Part IV. 2.2: Use of certain products and substances in processing of food.

## 2.1. General provisions applying to all ingredients

It should be noted that some general provisions of the EU Organic Regulation apply to any kind of ingredient including flavourings that are used in organic foods, such as the following:

- the use of ingredients consisting of, or obtained from or by GMOs (Art. 11) is prohibited;
- the use of ingredients containing or consisting of engineered nanomaterials is excluded (Art. 7 (e));
- the use of ionising radiation is equally prohibited (Art. 9).

## 2.2. General provisions for the min. 95% content of organic agricultural ingredients (=“min. 95%-rule”)

Recital (75) of the EU Organic Regulation states that processed food should be labelled as organic only where all or almost all of the ingredients of agricultural origin are organic. Detailed requirements are laid down in Art. 30: i.e. according to Art. 30(5)(a)(ii) at least 95% (by weight) of the agricultural ingredients of an organic product must be organic (= so called “min. 95%-rule”).

The calculation only includes ingredients of agricultural origin. In the processed organic foods the organic agricultural ingredients need to sum up to at least 95%. Non-organic agricultural ingredients can be contained up to a limit of 5%. However only permitted non-agricultural ingredients may be used. Ingredients that are not of agricultural origin are not included in the calculation.

## 3. Specific provisions in relation to flavourings

The new Organic Regulation offers two options with regard to the use of flavourings in organic foods: “organic suitable flavourings”<sup>2</sup> and “organic flavourings”.<sup>2</sup>

According to the EU-Commission [see letter<sup>1</sup>]:

- *“only flavourings, which are labelled according to Article 16(4) (“Natural <X> Flavourings”), may be used in the processing of organic food products.”*
- Consequently, flavourings corresponding to Article 16(5) (“Natural <X> Flavourings with Other Natural Flavourings”) and to Article 16(6) (“Natural Flavourings”) cannot be used. The same restriction applies to flavourings labelled as “natural flavouring substances” (according to Art. 16(3)).

### 3.1. Overall Authorisation for Using “Organic Suitable Flavourings in Organic Foods”

The authorisation for using flavourings in organic foods (hereinafter referred to as “organic suitable flavourings” for organic foods) is provided by point 2.2.2 of Annex II Part IV of the Organic Regulation.

#### a) Specific requirements for Flavourings

EU Organic Regulation – Annex II Part IV: Processed food production rules, Paragraph 2.2.2

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

*[...]*

*(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;*

This overall authorisation does not impose that the flavourings have to be organic. It refers to Regulation (EC) No 1334/2008 on flavourings (EU Regulation on Flavourings) and restricts the use of the flavouring to “natural <X> flavourings” labelled in accordance with Art. 16(4) of the Flavouring Regulation.

b) Provisions on Food Ingredients/Additives (to be used in “organic suitable flavourings” – e.g. as carriers<sup>3</sup>)

According to the Flavouring Regulation (EC) No 1334/2008 – Art. 3(4) and Recital (22):

*Flavourings may contain food additives as permitted by Regulation (EC) No 1333/2008 and/or other food ingredients incorporated for technological purposes such as for their storage, standardisation, dilution or dissolution and stabilisation.*

Provided that these food ingredients and additives are used in accordance with Article 3(4) of the EU Regulation on Flavourings, they are an integral part of the flavourings as also recognised/acknowledged by the EU-Commission (see letter from the EU-Commission<sup>1</sup>). As a consequence, they are covered by the direct authorisation provided by point 2.2.2 (b) of Annex II Part 4 of the Organic Regulation.

Additives permitted for use in flavourings are listed in the Annex III – Part 4 of the Additives Regulation (EC) No 1333/2008<sup>4</sup>. The other food ingredients in flavourings do not require a specific permission.

For an illustration of a typical example of an “organic suitable flavouring” see Annex I.

### 3.2. Overall Authorisation and Requirements for Using “Organic Flavourings”

a) Specific Requirements for Flavourings

The specific requirements for flavourings in relation to the so-called “Organic Flavourings” are stipulated in Article 30 of the Regulation.

**EU Organic Regulation – Article 30 – Use of terms referring to organic production, Paragraph 5:**

*5. For processed food, the terms referred to in paragraph 1 may be used:*

*(a) in the sales description, and in the list of ingredients where such a list is mandatory pursuant to Union legislation, provided that:*

*[...]*

*(iii) in the case of flavourings, they 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;*

In general, the Organic Regulation restricts the use of the flavouring to “natural <X> flavourings” labelled in accordance with Art. 16(4) of the Flavouring Regulation (see also above).

In addition, without prejudice to the application of the 95%-rule (see next section) Article 30, paragraph 5(a)(iii) requires that the **flavouring components**, and carriers of organic flavourings must be organic.

The use of non-organic flavouring components (within the 5% limit in weight of the flavouring components) is covered by the general authorisation granted at point 2.2.2 (b) of Annex II part IV of the Organic Regulation.

Point 2.2.2 provides a “direct” authorisation for the use of flavourings. Flavourings will not be authorised pursuant to Articles 24 and 25: no listing in annexes, no authorisation granted by Member State.

<sup>3</sup> Carriers are defined in Annex I point 5 of Regulation (EC) No 1333/2008 on food additives: ‘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;

<sup>4</sup> Regulation (EU) No 1130/2011 amending Annex III to Regulation (EC) No 1333/2008 food additives by establishing a Union list of food additives approved for use in food additives, food enzymes, food flavourings and nutrients, PART 4: Food additives including carriers in food flavourings.

#### b) Provisions on non-organic Food Ingredients/Additives for Organic Flavourings

According to the EU Organic Regulation (Art. 30(5)(a)) and the most recent letter from the EU-Commission<sup>1</sup> "*flavourings can be labelled organic when all of the flavourings components and carriers of flavouring components are organic*" without prejudice to the application of the 95%-rule (see next section).

The term "carrier" can be understood as all ingredients contained in the non-flavouring part of a flavouring (i.e. food ingredients and additives used as carriers but also other additives, e.g. anti-caking agents). The use of non-organic food ingredients and additives requires authorisation in accordance with the provisions of Article 24(2) and (4) of the Organic Regulation (see Annex II). Organic agricultural food ingredients in organic flavourings do not require a specific permission.

For an illustration of the calculation rule for an "organic flavouring" see Annex II.

## 4. Application of the "min. 95%-rule" to the organic processed foods

### 4.1. "Min 95%-Rule" Applied to the Organic Foods: Consideration of Flavourings as Agricultural Ingredients

The EU Organic Regulation (Article 30(5)(a)) provides provisions on the use of terms referring to organic production in the labelling of processed food. This article must be read in conjunction with Paragraph 2.2.4 of Annex II Part IV – Processed food production rules:

Article 30(5)(a)(ii): "*at least 95 % of the agricultural ingredients of the product by weight are organic; and*"

[...]

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

[...]

*(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;*

[...]"

Article 30(5) foresees that at least 95% (by weight) of the agricultural ingredients of organic foods shall be organic. For the purpose of that calculation, the organic food producers shall not consider as agricultural ingredients the preparations and substances mentioned in Annex II Part IV, 2.2.2 (a), (c), (d), (e), and (f).

As flavourings are not mentioned (flavourings are defined in point 2.2.2 (b)), they shall be considered as agricultural ingredients and therefore need to be considered for the calculation defined in Article 30(5) (so-called "min 95% rule").

### 4.2. "Min 95%-Rule" Applied to Organic Suitable Flavourings

The "organic suitable flavourings" account as a whole for the maximum 5% of non-organic agricultural ingredients (see section 2.2).

### 4.3. "Min 95%-Rule" Applied to Organic Flavourings: Consideration of Flavourings as Processed Foods

The provisions for processed foods are stipulated in Art. 30(5)(a)(iii):

*(iii) in the case of flavourings, they 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*

As noted in the letter from the EU-Commission:

*If produced organically, flavourings are included in the 95% by weight of the product which are organic according to Article 30(5)(ii).*

*[...]*

*Carriers and flavouring components are processed food, for which provisions referred to in Article 30 (5) (ii) of Regulation (EU) 2018/848 apply. Carriers may be considered as organic provided that at least 95% by weight of the agricultural ingredients of the carriers are organic. Similarly, flavouring components may be considered as organic if at least 95% by weight of the agricultural ingredients aromatic components are organic.*

As acknowledged by the EU-Commission, flavourings consist of two distinct parts: on the one hand, flavouring components and on the other hand non-flavouring ingredients (incl. carriers and additives), and the 95%-rule applies to both parts. For a schematic representation of organic flavourings, we refer to the Annex II.

EFFA Secretariat

26 June 2019

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Annex I: Example of “organic suitable flavouring”: natural lemon flavouring (taken from EFTA Guidance Document Annex XI):

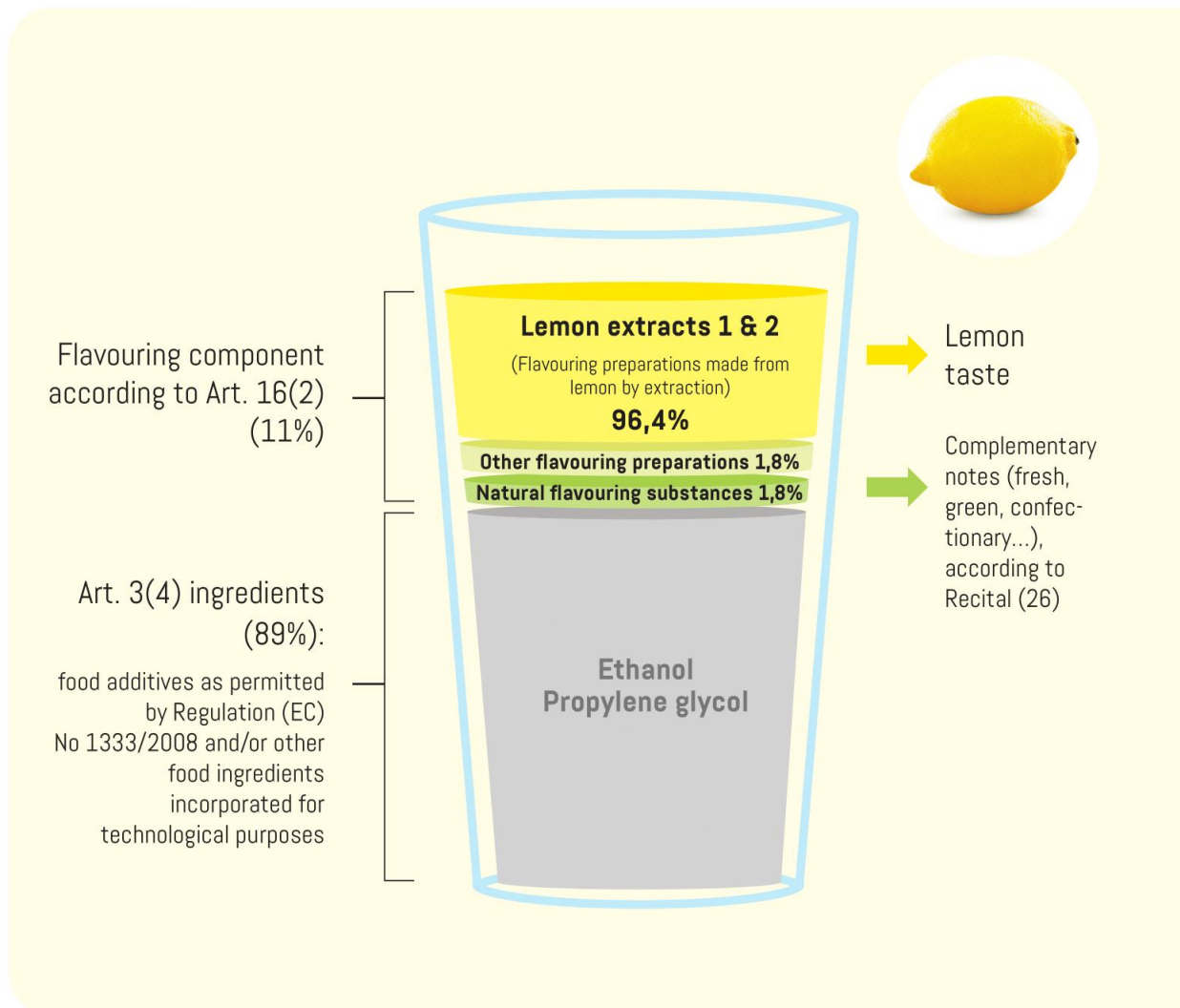
Part of the flavouring	Ingredients (Flavouring component and other ingredients)		Quantity / 100g flavouring	Quantity % of the flavouring component	
Flavouring component according to Art. 16(2)	Flavouring preparation	Lemon extract n°1*	10,5g	95,5%	96,4% w/w of the flavouring component issued from the named source (lemon)
	Flavouring preparation	Lemon extract n°2*	0,1g	0,9%	
	Flavouring preparation	Lime extract	0,1g	0,9%	3,6% w/w of the flavouring component from other preparations and substances not issued from the named source (lemon)
	Flavouring preparation	Peppermint extract	0,1g	0,9%	
	Natural flavouring substance	Beta-pinene	0,2g	1,8%	
Art. 3(4) ingredients	Solvents and/or carriers	Ethanol, Propylene glycol	89g		
<b>Total = 100g</b>					

100%

Table with the composition of the ingredients

\* "extracts" = Flavouring preparations made from lemon by extraction

Schematic presentation of the flavouring



Annex II: Visualisation of the composition of an organic flavouring and the application of the 95%-rule (according to the Organic Regulation and the Commission letter to EFFA)



\* Food additives marked with an asterisk in the Organic Regulation (currently in Annex VIII of Regulation (EC) 889/2008), shall be calculated as ingredients of agricultural origin. These additives shall therefore be included in the calculation of the "95%-rule".

§ Additives without asterisk are allowed as they are included in Annex VIII part A of Regulation (EC) 889/2008, but are out of the calculation (not regarded as ingredients of agricultural origin).



## Annex III: EFA interpretation paper on the prohibition of GMOs according to the EU Organic Regulation, in relation to non-organic ingredients of flavourings for organic foodstuffs

Regulation (EU) 2018/848 on organic production (which replaces Regulation (EC) No 834/2007 as from 1<sup>st</sup> January 2022) excludes the use of GMOs in organic production. This prohibition applies also to non-organic flavourings that can be used in organic foods (i.e. “organic suitable flavourings”).

EFA understands that **the provisions on GMOs in the new Regulation (EU) 2018/848 remain the same as in the current Regulation (EC) No 834/2007.**

**However, the Organic Regulation refers to specific definitions and provisions which require some explanation in the context of flavourings to be used in organic foods.**

The scope of this paper is limited to all non-organic ingredients used in flavourings for organic foods<sup>1</sup>.

### 1. Provisions on GMOs

The provisions on GMOs in the New Organic Regulation (EU) 2018/848 (hereinafter referred to as the “Organic Regulation”) are found in Recital (23), Article 3 (definitions), Article 5 (General principles), Article 11 (Production rules – prohibition of the use of GMOs) and Article 30(4) (Labelling).

### 2. Analysis of the provisions

According to Article 11(1) of the Organic Regulation, it is forbidden to use 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, products<sup>2</sup>:

- Consisting of GMOs or containing GMOs;
- Produced from GMOs;
- Produced by GMOs.

Article 11(4) specifies that, **for non-organic products used in organic food**, the food producer should ask his suppliers to confirm that these non-organic products are not produced from or by GMOs.

**Conclusion: All non-organic ingredients of flavourings used in organic food shall not contain GMOs and shall not be produced from GMOs nor by GMOs.**

**EFA interpretation:** 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).

### 3. Definitions (Regulation (EU) 2018/848)

“**Genetically modified organism (GMO)**”, a genetically modified organism as defined in point (2) of Article 2 of Directive 2001/18/EC of the European Parliament and of the Council which is not obtained through the techniques of genetic modification listed in Annex I.B to that Directive;

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<sup>1</sup> For organic ingredients, the provisions are stricter than for non-organic suitable flavouring ingredients. Indeed, in this case, each production step shall fulfill the Art. 11(1) provisions.

<sup>2</sup> Art. 11(1) covers only organic flavourings. Non-organic ingredients of flavourings used in organic foods are covered by Art. 11(4). The food producer can rely on the vendor declaration for these ingredients.

“Produced from GMOs”, derived in whole or in part from GMOs but not containing or consisting of GMOs;

“Produced by GMOs”, derived by using a GMO as the last living organism in the production process, but not containing or consisting of GMOs nor produced from GMOs.

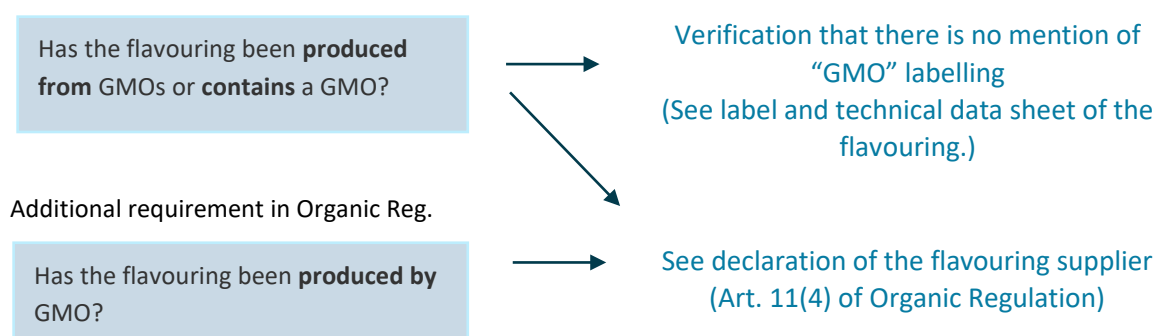
Regulations (EC) No 1829/2003 and No 1831/2003 (“GMO-Regulation”) do not define “produced by GMOs”. This is only defined within the Organic Regulation. However, the GMO Regulation mentions, without defining it, “produced with the help of”. For example, “food [...] which are manufactured with the help of a genetically modified processing aid [...]” (Whereas (16)). “Produced by” and “Produced with the help of” cannot be considered as equal.

**EFFA interpretation:** “Produced by” is a very specific “subset” of “produced with the help of”.

## 4. Obligation of the manufacturer of organic foods (users of non-organic ingredients/flavourings)

According to Article 11(2) and 11(3) of the Organic Regulation, the manufacturer of organic foods may rely on the labels and traceability carried out pursuant to the GMO-Regulation (except if a non-conformity is suspected) of a purchased product, regarding the fact this ingredient is **not a GMO nor produced from GMOs**.

Manufacturers of organic foods using flavourings are therefore led to check two points:



### What is a flavouring (or an ingredient of a flavouring) produced ‘by GMO’?

It is a flavouring (or an ingredient of a flavouring) *produced by a process in which the last living organism used is a GMO, but not consisting of GMO and not containing a GMO, nor produced from GMO*.

### What is the meaning of the term “last living organism”?

Directive 2001/18/EC defines what is an organism:

*“Organism”*: any biological entity capable of replication or of transferring genetic material;

It is therefore microorganisms, plants, live animals, viruses. Enzymes are not (living) organisms.

## 5. Examples

### 5.1. Case N°1 – Ingredients of a flavouring produced by fermentation using a Genetically Modified Microorganism (GMM)<sup>3</sup>

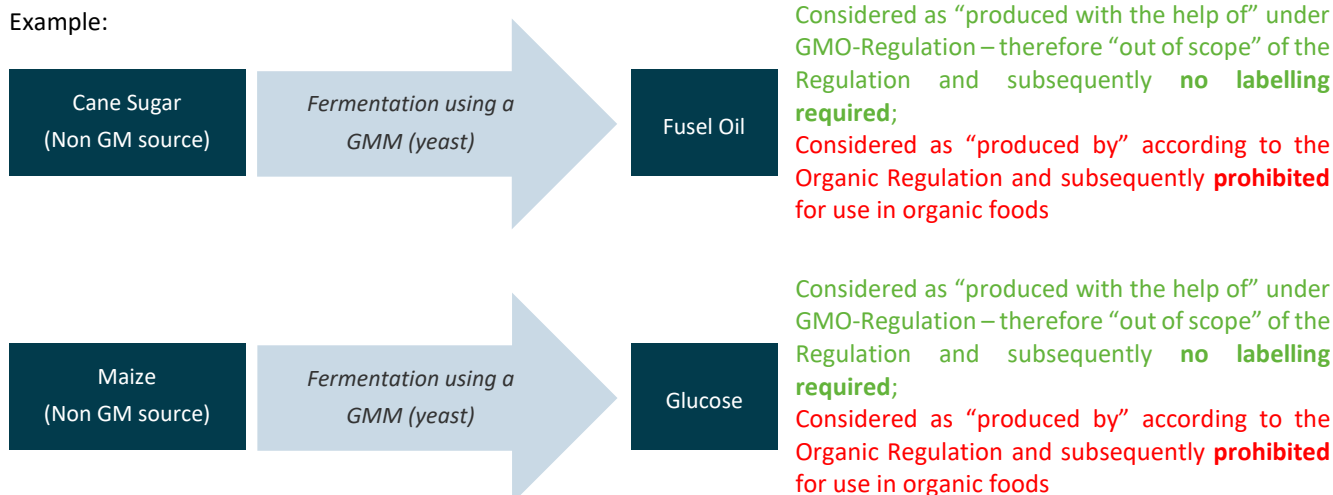
A GMM is a genetically modified living organism. If the GMM is the last living organism used in the manufacture of a flavouring ingredient (e.g. a flavouring substance or a flavouring preparation or carrier/solvent – see examples below), then this flavouring ingredient will be considered as produced by GMO.

The last living organism used is the GM microorganism. Flavouring ingredients produced by fermentation using a GMM therefore are considered as “produced by GMO” according to the EU Organic Regulation. These flavouring ingredients are

<sup>3</sup> Growing media used to produce GMM are out of the scope of the GMO provisions of the Organic Regulation.

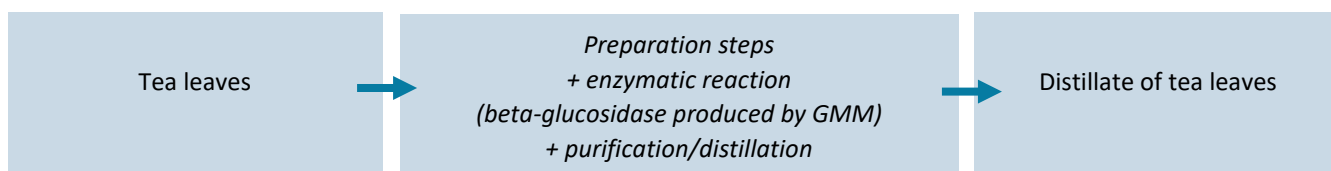
prohibited in flavourings for organic foods (irrespective of whether traces of the GMM are present or not, irrespective of whether the GMM have been used in a confined environment or not).

Example:

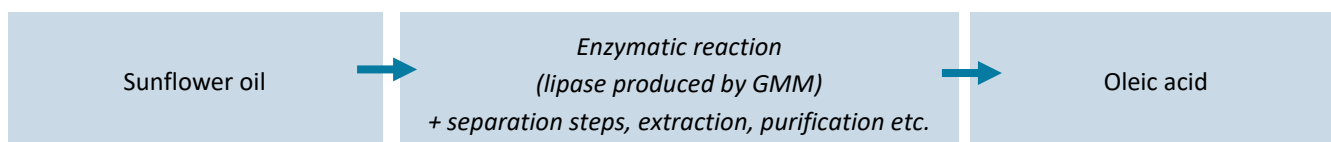


## 5.2. Case N°2 – Flavouring preparation or Natural flavouring substance produced through enzymatic reaction with the help of an enzyme produced by a GMM

An enzyme is not a living organism. The last living organism must be identified: it could be for example the plant (vegetable source) used as starting raw material.



The last living organism is tea. It should not be a GMO.



The last living organism is sunflower. It should not be a GMO.

The GMM is the last living organism in the enzyme manufacturing process but not in the manufacturing process of the flavouring preparation or the natural flavouring substance. Therefore, the flavouring preparation or the natural flavouring substance is not considered as “produced by”.

Under GMO Regulation, processing aids like enzymes are by definition out of scope. Therefore, flavouring components (i.e. flavouring preparation or natural flavouring substance) produced with the help of enzymes are out of scope and subsequently no GMO-labelling is required.

Flavouring preparations and natural flavouring substances produced with the help of an enzyme produced by a GMM are not considered as “produced by”, therefore allowed in organic foods.

## Summary table

Flavouring ingredient (i.e. flavouring components & non-flavouring components)	GMO Regulation <i>GMO Labelling of the flavouring</i>	Organic Regulation <i>Flavouring use (by the producer of organic foods)</i>
Ingredient consisting of or containing GMO or containing an ingredient consisting of or containing GMO	<b>Labelled</b>	<b>Prohibited</b>
Ingredient produced from GMO or containing an ingredient produced from a GMO	<b>Labelled</b>	<b>Prohibited</b>
Ingredient produced by GMM (fermentation) – See Case N°1	Out of scope and subsequently not labelled (if confined conditions, GMM absent in the flavouring)	<b>Prohibited</b> (even if confined use and GMM not present)
Ingredient produced with the help of an enzyme produced by GMM – See Case N°2	Out of scope and subsequently not labelled	<b>Allowed</b>

## Extracts of Regulation (EU) 2018/848

- **Whereas (23):**

*The use of ionising radiation, animal cloning and artificially induced polyploid animals or genetically modified organisms ('GMOs'), as well as products produced from or by GMOs, is incompatible with the concept of organic production and consumers' perception of organic products. Such use should therefore be prohibited in organic production.*

- **Article 3**

### Definitions

*For the purposes of this Regulation, the following definitions apply: [...]*

*(58) 'genetically modified organism' or 'GMO' means a genetically modified organism as defined in point (2) of Article 2 of Directive 2001/18/EC of the European Parliament and of the Council (1) which is not obtained through the techniques of genetic modification listed in Annex I.B to that Directive;*

*(59) 'produced from GMOs' means derived in whole or in part from GMOs but not containing or consisting of GMOs;*

*(60) 'produced by GMOs' means derived by using a GMO as the last living organism in the production process, but not containing or consisting of GMOs nor produced from GMOs;*

- **Article 5**

### General Principles

*Organic production is a sustainable management system that is based on the following general principles: [...]*

*(f) (iii) exclude the use of GMOs, products produced from GMOs, and products produced by GMOs, other than veterinary medicinal products;*

- **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 of the Council (1) or Regulation (EC) No 1830/2003 of the European Parliament and of the Council (2) 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 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.*

## Annex IV: EFA Position Paper on the application of non-concomitance rule from the EU Organic Regulation to flavourings

The “non-concomitance rule” of the new EU organic Regulation states that an organic ingredient shall not be present together with the same ingredient in non-organic form [in organic foods]. It is one of the general rules taken over from old Regulation.

A “natural <X> flavouring” is not the same ingredient as the food “X” or food ingredient derived from “X”. Therefore, a food producer may use together a non-organic “natural <X> flavouring” and the organic food “X” resp. an organic food ingredient derived from “X” in an organic foodstuff.

The flavouring part of an organic “natural <X> flavouring”, that is used in an organic food, may contain different and various natural flavouring substances and/or flavouring preparations derived from the same kind of source “X”. Within the conditions allowed by the EU Organic Regulation regarding formulation, some of these may be non-organic.

### 1. Introduction

Regulation (EU) No 2018/848 (hereinafter referred to as the “EU Organic Regulation”) was published on 14<sup>th</sup> June 2018 and entered into force on 17<sup>th</sup> June 2018. It will apply as of 1<sup>st</sup> January 2022. EFA published in June 2019 its Guidance Document on the new provisions regarding flavourings<sup>1</sup>.

The EU Organic Regulation provides the general provisions regarding organic processed food. One of those is the so-called “non-concomitance rule”. The current paper expresses EFA’s interpretation regarding the application of this rule to flavourings used in organic foods.

### 2. Non-concomitance rule

The “non-concomitance rule” is provided by point 2.1(b) of Annex II Part IV of the Regulation (EU) No 2018/848.

*2.1. The following conditions 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 [in organic foods].*

This rule with the same wording was also set in Regulation (EC) No 834/2007, i.e. the former Organic Regulation, in Article 19.2(d).

### 3. Application to Flavourings

#### 3.1. Application to Flavourings Used in an Organic Foodstuff

The non-concomitance rule applies to organic processed foods including organic foods with added flavourings. In this context the following question was raised:

- Is the joint use of a non-organic “natural <X> flavouring” with the organic food “X” respectively a food ingredient derived from “X” allowed regarding this rule?

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<sup>1</sup> EFA Guidance Document on the new EU Organic Regulation in relation to flavourings

*Examples: organic lemon soft drink (organic lemon juice + non-organic natural lemon flavouring), organic apricot yoghurt incorporating pieces of organic apricots + non-organic natural apricot flavouring, ...*

The Organic Regulation refers to the ingredient definition according to the Food Information to Consumers (FIC) Regulation (EU) No 1169/2011. Processed foodstuffs are usually made of several ingredients as defined by Art. 2.2(f) of the FIC Regulation.

Flavourings, as defined in the “EU Regulation on Flavourings” (Regulation (EC) No 1334/2008), are not intended to be consumed as such.

The flavouring part of a “natural <X> flavouring” is mainly derived from the “source material X” as defined at Art. 3.2(j) of the “EU Regulation on Flavourings”. The non-concomitance rule however refers to an “ingredient” as defined in the FIC Regulation and not to “source material” as defined by the EU Regulation on Flavourings.

Coming back to the example above, an organic lemon soft drink may be made of the following ingredients: water, sugar, lemon juice, natural lemon flavouring, etc ... The lemon juice and the natural lemon flavouring are derived from the same kind of source material i.e. lemon – they are however considered as different ingredients of the soft drink.

**A “natural <X> flavouring” is not the same ingredient (within the meaning of the non-concomitance rule) as the food “X” respectively a food ingredient derived from “X”. Therefore, a food producer may use together a non-organic “natural <X> flavouring” and the organic food “X” respectively food ingredient derived from “X” in an organic foodstuff.<sup>2</sup>**

Moreover, the EU Commission clarified<sup>3</sup> that within the spirit of the EU Organic Regulation organic suitable “natural <X> flavourings” as well as organic “natural <X> flavourings” are permitted. Therefore, in accordance with the EU Organic Regulation, it is allowed to use a non-organic natural lemon flavouring in an organic lemon soft drink.

### 3.2. Application to the Flavouring Part of Organic Flavourings

As the non-concomitance rule applies to organic processed foods, it applies also to organic flavourings. The flavouring part of an organic natural <X> flavouring may contain different and various ingredients, i.e. min. 95% natural flavouring substances and/or flavouring preparations, from the same source “X”.

*Examples of ingredients of the flavouring part of an organic flavouring: lemon oils, lemon distillate, and natural flavouring substances [e.g. limonene] from lemons*

These flavouring preparations and natural flavouring substances are derived from the same kind of source “X”, but they are considered as different ingredients of the “natural <X> flavouring”.

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<sup>2</sup> The joint use of a non-organic “natural <X> flavouring” and the organic ingredient “X” in organic food is allowed as long as the other provisions of the EU Organic Regulation are fulfilled, especially the so-called “min. 95% rule”. (Art. 30(5)(a)(ii) of the EU Organic Regulation)

<sup>3</sup> See letter from the EU-Commission (Mrs N. Sauze-Vandevyver, DG AGRI) from 04/03/2019 to EFFA-Secretariat in Appendix I of the [EFFA Guidance Document on the new EU Organic Regulation in relation to flavourings](#)

In the below example of an organic “natural <X> flavouring”, the peel oil from Sicilian lemon, lemon fruit distillate and terpeneless lemon oil may be organic and the limonene (from lemon) non-organic as they are different ingredients.<sup>4</sup>

Part of the flavouring	Ingredients (Flavouring component and other ingredients)		Quantity / 100g flavouring	Quantity % of the flavouring component	
Flavouring component according to Art. 16(2)	Flavouring preparation	Peel oil from Sicilian lemon *	40,0g	40,0%	97,6% w/w of the flavouring component issued from the named source (lemon)
	Flavouring preparation	Lemon fruit distillate *	33,0g	33,0%	
	Flavouring preparation	Terpeneless lemon oil *	24,4g	24,4%	
	Natural flavouring substance	Limonene from lemon	0,2g	0,2%	
	Flavouring preparation	Orange oil *	0,1g	0,1%	
	Natural flavouring substances	Linalool Geranyl acetate Geraniol	2,3g	2,3%	
Art. 3(4) ingredients	Solvents and/or carriers	None	0g		2,4% w/w of the flavouring component from other preparations and substances not issued from the named source (lemon)
* organic ingredients			Total = 100g		

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<sup>4</sup> Without prejudice to the application of the Art. 30(5)(a)(iii) of the EU Organic Regulation regarding the formulation of organic flavourings





**EUROPEAN COMMISSION**  
DIRECTORATE-GENERAL FOR AGRICULTURE AND RURAL DEVELOPMENT

Directorate B. Quality, Research & Innovation, Outreach  
**Director**

Brussels,  
PP/sn/agri.ddg1.b.4(2019)1202377

Dear Mr Demyttenaere,

Following the meeting of 2 October 2018, you had with Unit B4, I am writing to address your request of clarifications regarding the new provisions on flavourings laid down in Regulation (EU) 2018/848<sup>1</sup> on organic production.

Authorisation for using flavourings in the processing of organic food products

- Overall authorisation

The authorisation for using flavourings in organic food is provided by point 2.2.2 (b) of Annex II part IV of the Regulation (EU) 2018/848.

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

*(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.”*

Point 2.2.2 provides a "direct" authorisation for the use of flavourings. Flavourings will not be authorised pursuant to Articles 24 and 25: no listing in annexes, no authorisation granted by Member State. This overall authorisation does not impose that the flavourings have to be organic.

- Products and substances which may be used

The use of flavourings is conditional to the respect of specific provisions of the Regulation (EC) No 1334/2008.

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<sup>1</sup> Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007 – OJ L 150, 14.6.2018 p.1

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Only substances and products defined in points (c) and (d)(i) of article 3(2) of Regulation (EC) No 1334/2008 may be used:

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

(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;”

Only the substances and products that have been labelled as natural flavouring substances or natural flavouring preparations in accordance with Article 16(2), (3) and (4) of Regulation (EC) No 1334/2008 may be used.

“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’.”

Other categories of products and substances, in particular those listed in Article 16(5) and 16(6) of the Regulation (EC) No 1334/2008 cannot be used as flavourings.

Article 16(5) refers to natural flavourings where *“the flavouring component is partially derived from the source material referred to, the flavour of which can easily be recognised.”*

Article 16(6) refers to natural flavourings where *“the flavouring component is derived from different source materials and where a reference to the source materials would not reflect their flavour or taste.”*

To sum up:

- Only the substance that have been labelled in accordance with Article 16(2) (*flavouring preparations and/or natural flavouring substances*), Article 16(3) (natural substances) and (not or) Article 16(4) (flavouring obtained exclusively of by at least 95% from the source material referred to) may be used.
- Flavourings corresponding to Article 16(5) (flavouring component partially derived from the source referred to, the flavour of which can be easily recognised) and to Article 16(6) (flavouring component derived from different source materials and where a reference to the source materials would not reflect their flavour of taste) cannot be used.

Consequently, in more practical terms, only flavourings, which are labelled according to Article 16(4), may be used in the processing of organic food products. These flavourings should be obtained by at least 95% from the source material referred to. The remaining 5 % could include natural substances that are labelled according to Article 16(3).

- Authorisation for carriers

Flavourings are made of a flavouring component and of carriers of flavouring component. "Carriers" are defined in Annex I point 5 of Regulation (EC) No 1333/2008 on food additives:

*"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;"*

In practice, carriers are made of food ingredients (sugar, oils, water, alcohols...) and food additives as permitted by (EC) Regulation No 1333/2008, in particular in Part 4 of Annex III listing the "*Food additives including carriers in food flavourings*".

The carriers and additives which have only a technological function in the flavourings (anticaking agent, emulsifier to stabilise a flavouring emulsion...) and which do not impact the quality of the food product are not labelled as such in the flavourings nor in the food product. These carriers and additives are an integral part of the flavourings and, as a consequence, are covered by the direct authorisation provided by point 2.2.2 (b) of Annex II Part IV, as long as they are listed in the Annex III of the Regulation (EC) No 1333/2008.

The authorisation to use any other food additives which will impact the food products in which the flavourings are incorporated (colour...) and which are subject to a specific labelling in the flavourings and the food products, should be provided by Article 24 (2)(a) (current Annex VIII, Section A – Food additives, including carriers, of (EC) Regulation No 889/2008).

#### Conditions for using non-organic flavourings in the processing of organic food products

According to Article 30 (5) (ii) of Regulation (EU) 2018/848:

*"For processed food, the terms referred to in paragraph 1 may be used:*

- (a) in the sales description, and in the list of ingredients where such a list is mandatory pursuant to Union legislation, provided that:*
- (ii) at least 95 % of the agricultural ingredients of the product by weight are organic;“*

Annex II part IV 2.2.2 of Regulation (EU) 2018/848 lists the products and substances which may be used in the processing of food:

- “(a) preparations of micro-organisms and food enzymes...  
(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;  
(c) colours for stamping meat...  
(d) natural colours and natural coating substances...  
(e) drinking water and organic or non-organic salt...  
(f) minerals (trace elements included), vitamins...”*

According to Annex II part IV, point 2.2.4.:

- “For the purpose of the calculation referred to in Article 30(5), the following rules shall apply:  
(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;”*

Flavourings are referred to in point 2.2.2 (b); they are not included in the list of preparations and substances which shall not be calculated as agricultural ingredients. As a matter of consequence, flavourings are to be calculated as agricultural ingredients and are therefore to be included in the 5 % by weight of the product which could be non-organic according to Article 30(5)(ii) of Regulation (EU) 2018/848.

If produced organically, flavourings are included in the 95% by weight of the product which are organic according to Article 30(5)(ii). However, if only the carriers are organic, and not the flavouring components, flavourings are to be calculated on the basis of the total weight of the flavourings (flavouring component + carriers).

#### Specific provisions applying to organic flavourings

The conditions referred to in Article 30 (5)(a) of Regulation (EU) 2018/848 apply to organic flavourings as processed food.

- “5. For processed food, the terms referred to in paragraph 1 may be used:  
(iii) in the case of flavourings, they 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”*

Flavourings can be labelled organic when all of the flavourings components and carriers of flavouring components are organic. This provision considers two distinct parts of the flavourings: on the one hand, carriers and on the other hand, flavouring components.

Carriers are food ingredients constituting the non-flavouring part of the flavourings, possibly together with additives. Carriers are responding to a technological need (to facilitate the mixture of the aromatic components, their dissolution, preservation...).

Flavouring components are a mixture of natural aromatic substances and natural aromatic preparations conferring the taste and smell of flavouring.

Carriers and flavouring components are processed food, for which provision referred to in Article 30 (5) (ii) of Regulation (EU) 2018/848 apply. Carriers may be considered as organic provided that at least 95% by weight of the agricultural ingredients of the carriers are organic. Similarly flavouring components may be considered as organic if at least 95% by weight of the agricultural ingredients aromatic components are organic.

The use of non-organic carriers and additives (within the 5 % limit in weight of the carriers) should be authorised in accordance with the provisions of Article 24 (2) and (4) of Regulation (EU) 2018/848.

The use of non-organic flavouring components (within the 5 % limit in weight of the flavouring components) are authorised in accordance with point 2.2.2. (b) of Annex II Part IV of Regulation (EU) 848/2018.

The present opinion expresses the view of the Commission services and does not commit the European Commission. In the event of a dispute involving Union law it is, under the Treaty on the Functioning of the European Union, ultimately for the European Court of Justice to provide a definitive interpretation of the applicable Union law.

Yours sincerely,

Nathalie SAUZE-VANDEVYVER