



Frequently asked questions ON ORGANIC RULES

Foreword

This document compiles questions and answers regarding the provisions of Regulation (EU) No 2018/848 and its secondary legislation.

This document is made available for information purposes only by the Commission services and is not a legally binding document. In the event of a dispute involving Union law, it is ultimately for the European Court of Justice to provide a definitive interpretation of the applicable Union Law.

It is important to underline that replies are addressing specific written questions, which have been summarised in this document and must be read within the restricted context of each question.

This document will be regularly updated and published on the website of the European Commission at the following address:

https://agriculture.ec.europa.eu/farming/organic-farming/organics-glance_en

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1. SUBJECT MATTER, SCOPE, DEFINITIONS

1) Can food supplements be organic?

Food supplements are food in accordance with the definition provided for Article 2(j) of Regulation (EC) No 178/2002 (General Food Law). Article 2(1) of Regulation (EU) No 2018/848 defines the scope of the organic legislation as applying to: *"the following products originating from agriculture, including aquaculture and beekeeping, as listed in Annex I to the TFEU and to products originating from those products, where such products are, or are intended to be, produced, prepared, labelled, distributed, placed on the market, imported into or exported from the Union:*

(a) live or unprocessed agricultural products, including seeds and other plant reproductive material;

(b) processed agricultural products for use as food;

(c) feed.

This Regulation also applies to certain other products closely linked to agriculture listed in Annex I to this Regulation, where they are, or are intended to be, produced, prepared, labelled, distributed, placed on the market, imported into or exported from the Union."

Hence, only food supplements produced from agricultural ingredients fall under the scope of the organic regulation and can be labelled as organic

Food supplements produced from vitamins and minerals do not fall under the scope of the EU organic legislation and cannot be labelled as organic.

2) Can Kombucha also known as "scooby" be certified as organic?

Kombucha culture or scoby is a symbiotic colony of bacteria and yeast.

Processed agricultural products for use as food and yeast fall under the scope of the EU organic legislation as set out in Article 2(1) of Regulation (EU) No 2018/848. Therefore, kombucha tea and scoby can be certified as organic provided that the rules for the production and labelling of processed food are complied with.

Annex II part IV point 2.2.2. of Regulation (EU) No 2018/848 authorises the use of *"preparations of micro-organisms and food enzymes normally used in food processing"*.

If kombucha tea is produced by adding to organic tea a preparation of yeast and micro-organisms and enzymes, which could be considered as normally used in food processing, the beverage can be certified as organic.

However, if kombucha tea is produced by adding scoby (yeast and bacteria) as an ingredient, the scoby (as ingredient) has to comply with the production rules of organic yeast set out in Annex II Part VII of Regulation (EU) No 2018/848. If the rules on production of organic yeast are respected, the scoby can be certified as organic and added as an ingredient in the production of organic beverages. As a result, kombucha tea and scoby can be certified as organic, provided that the rules for the production of organic processed food are respected and complied with.

3) Can the term "bio" be used on the label of detergents?

The scope of the EU organic legislation is set out in Article 2(1) of Regulation (EU) No 2018/848 and covers unprocessed agricultural products and processed agricultural products for use as food.

Detergents are not unprocessed or processed agricultural products for use as food, and as a consequence, detergents do not fall under the scope of the EU organic legislation and can be neither certified as organic, nor labelled or advertised using the EU organic logo.

However, Article 30(1) of Regulation (EU) No 2018/848 provides that: *"In particular, the terms listed in Annex IV and their derivatives and diminutives, such as 'bio' and 'eco', whether alone or in combination, may be used throughout the Union and in any language listed in that Annex for the labelling and advertising of products referred to in Article 2(1) which comply with this Regulation."*

Moreover, Article 30(2) lays down : *"For the products referred to in Article 2(1), the terms referred to in paragraph 1 of this Article shall not be used anywhere in the Union, in any language listed in Annex IV, for the labelling, advertising material or commercial documents of a product which does not comply with this Regulation."*

Furthermore, no terms, including terms used in trademarks or company names, or practices shall be used in labelling or advertising if they are liable to mislead the consumer or user by suggesting that a product or its ingredients comply with this Regulation."

Therefore, the EU organic legislation does not prevent the use of the terms that refer to the organic production method, such as "bio" or "eco", in products not related to agricultural products or not in the scope of the EU organic legislation, or whenever not liable to mislead the consumers.

4) Can alcoholic drinks be certified as organic?

In the European Union, alcoholic beverages having an alcohol content of more than 15% volume are governed by Regulation (EU) 2019/787 (EC) (Spirit drinks Regulation). Furthermore, spirit drinks, like all alcoholic beverages, are considered as foodstuffs and are subject to general and sector specific foodstuff legislation.

Article 2(1) of Regulation (EU) No 2018/848 sets out the scope of the EU organic legislation as follows: *"This Regulation shall apply to the following products originating from agriculture, including aquaculture and beekeeping, as listed in Annex I to the TFEU and to products originating from those products, where such products are, or are intended to be, produced, prepared, labelled, distributed, placed on the market, imported into or exported from the Union:*

(a) live or unprocessed agricultural products, including seeds and other plant reproductive material;

(b) processed agricultural products for use as food;

(c) feed;

This regulation also applies to certain other products closely linked to agriculture listed in Annex I to this regulation where they are, or are intended to be, produced, prepared, labelled, distributed, placed on the market, imported into or exported from the Union."

Spirit drinks are made out of ingredients of agricultural origin falling within the scope of Regulation (EU) No 2018/848. Therefore, spirit drinks can be certified as organic, provided that the processing of such foodstuff complies with the rules and principles applicable to the processing of organic food laid down in the EU organic legislation referred above.

5) Can a fertiliser be certified as organic?

No. Article 2(1) of Regulation (EU) No 2018/848 states the products which are in the scope of the EU organic legislation, and fertilisers are not included in this list of products and therefore cannot be certified as organic.

However, they can be used as input in organic production and under Article 24(1) of Regulation (EU) No 2018/848, the Commission may authorise certain fertilisers for use in organic production and include them in a restricted list. Annex II to Commission Implementing Regulation (EU) 2021/1165 lays down the list of fertilisers that can be used in organic production in the EU.

In addition, Article 9(3) requires that *" For the purposes and uses referred to in Articles 24 and 25 and in Annex II, only products and substances that have been authorised pursuant to those provisions may be used in organic production, provided that their use in non- organic production has also been authorised in accordance with the relevant provisions of Union law and, where applicable, in accordance with national provisions based on Union law "*.

Therefore, it is important to contact the Competent Authorities of the Member State in which the product is going to be marketed and used.

A list of these authorities is provided, per Member State, on the following link:

https://ec.europa.eu/agriculture/ofis_public/actors-ca/ca-list.html?lang=en

Finally, Article 31 of Regulation (EU) 2018/848 provides for the possibility to use a reference indicating that fertilisers authorised in accordance with Articles 9 and 24 have been authorised for use in organic production in accordance with Regulation (EU) 2018/848. The referred provision provides for a voluntary labelling option for which operators selling fertilisers, as authorised for use in organic production, are responsible.

6) Can mushrooms be certified as organic?

Mushrooms are covered by the scope of the EU organic legislation. Mushrooms are considered as plants for the purpose of the EU organic legislation even if mushrooms are not plants according to the current biological classification.

Thus, the general rules for plant production under Regulation (EU) No 2018/848 and specific rules laid down in its Annex II Part 1 point 2.1. are applicable.

7) Can the EU organic logo be used on organic Shea Butter cream?

No. Regulation (EU) No 2018/848 applies to products originating from agriculture, including aquaculture, which are intended for use as food or animal feed.

Therefore, cosmetics can be neither certified as organic under Regulation (EU) No 2018/848 nor labelled or advertised using the EU organic logo.

The production and labelling of organic cosmetics is not regulated at EU level. Member States might have national legislation in this regard. Therefore, it is important to contact National authorities in this matter. A list of these authorities is provided, per Member State, on the following link:

https://ec.europa.eu/agriculture/ofis_public/actors-ca/ca-list.html?lang=en

8) Can dried tobacco leaves be certified as organic?

No. Dried tobacco leaves are a processed product not for use as food or feed, and therefore cannot be certified as organic under Regulation (EU) No 2018/848.

Moreover, even if Member States might have national legislation or private standards, Article 13(1)(b) of Directive 2014/40/EU prohibits labelling of tobacco products with any element or feature suggesting that a particular tobacco product has organic properties.

9) Can spirulina be certified as organic?

Yes. Spirulina is traditionally identified as blue-green micro-algae belonging to genera *Arthrospira*¹. Algae are agricultural products and thereby fall within the scope of the EU organic legislation in accordance with Article 2(1)(a) of Regulation (EU) No 2018/848.

Regulation (EU) 2018/848 refers to algae, in particular under point 2 of part III of its Annex II, which provides for requirements for algae and states the following: *"In addition to the general production rules laid down in Articles 9, 10, 11 and 15, and where relevant in Section 1 of this Part, the rules laid down in this Section shall apply to the organic collection and production of algae. Those rules shall apply mutatis mutandis to the production of phytoplankton."*

10) Is there a possibility to certify essential oils as organic regardless of their final use?

Yes. Pursuant to its Article 2(1), Regulation (EU) No 2018/848 includes in its scope *"certain other products closely linked to agriculture listed in Annex I to this Regulation, where they are, or are intended to be produced, prepared, labelled, distributed, placed on the market, imported into or exported from the Union"*. Essential oils are listed in Annex I to Regulation (EU) No 2018/848 and are therefore within the scope of the EU organic legislation. Consequently, these products may be certified as organic regardless of their final use, subject to the respect of all the applicable provisions. For example, essential oils used as cosmetic products are also subject to the provisions of Regulation (EC) No 1223/2009² and, in particular, for labelling they are subject to its Article 20 laying down requirements on product claims.

11) Can a product made up of substrates for mushroom and tissues for growing be certified as organic?

Yes. Article 2 of Regulation (EU) 2018/848 lays down the scope of the EU organic legislation in the following terms: *"This Regulation applies to the following products originating from agriculture, including aquaculture and beekeeping as listed in Annex I to the TFEU and to products originating from those products, where such products are, or are intended to be produced, prepared, labelled, distributed, placed on the market, imported into or exported from the Union:"*

¹ <http://www.fao.org/3/a-az386e.pdf>

² Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products OJ L 342, 22.12.2009, p.59

- (a) live or unprocessed agricultural products, including seeds and other plant reproductive material;*
- (b) processed agricultural products for use as food;*
- (c) feed.*

This regulation also applies to certain other products closely linked to agriculture listed in Annex I to this Regulation, where they are, or are intended to be, produced, prepared, labelled, distributed, placed on the market, imported into or exported from the Union."

Edible mushrooms are vegetables (according to the combined nomenclature³) and are listed in Annex I to the TFEU. These products therefore fall under the scope of Regulation (EU) 2018/848.

The general rules on organic plant production and the specific rules regarding organic mushroom production (point 2.1. of Part I of Annex II to Regulation (EU) 2018/848) are applicable to edible mushroom production. These rules apply to the entire fungal body, including the mycelium. A product made up of substrates for mushroom and tissues for growing is considered "*reproductive material*" for mushroom production. It may be certified as organic, subject to the respect of all applicable rules.

For example, being reproductive material, point 1.8.2. of Part I of Annex II must be respected: "*To obtain organic plant reproductive material to be used for the production of products, other than plant reproductive material, the mother plant and where relevant other plants intended for plant reproductive material production, shall have been produced in accordance with this Regulation for at least one generation, or, in the case of perennial crops, for at least one generation during two growing seasons.*"

The mycelium to be used for edible mushroom production must therefore derive from a mother mycelium that has already been grown under the organic production rules and for at least one cycle. No other conversion period is necessary, as the conversion is linked to the soil parcel and, in accordance with point 2.1 of Part I of Annex II of Regulation (EU) 2018/848, substrates may be used in mushroom production if they are composed only of the components listed in that point.

12) Can mass catering be certified organic?

Yes, but only at national level under certain conditions.

Article 2(3) of Regulation (EU) No 2018/848 states that: "*Mass catering operations carried out by a mass caterer as defined in point (d) of Article 2(2) of Regulation (EU) No 1169/2011 are not subject to this Regulation except as set out in this*

³ Chapter 7 of Council Regulation (EC) 2658/87 on the tariff and statistical nomenclature and on the Common Customs Tariff includes edible mushrooms within "vegetables" (OJ L 256, 7.9.1987, p. 1).

paragraph. Member States may apply national rules or, in the absence thereof, private standards, on the production, labelling and control of products originating from mass catering operations. The organic production logo of the European Union shall not be used in the labelling, the presentation or the advertising of such products, and shall not be used to advertise the mass caterer."

13) Can a bakery or a butchery fall under the scope of the organic legislation?

Yes. A bakery or a butchery may fall under the scope of the EU legislation on organic production and labelling of organic products. For example, pursuant to Article 34(1) of Regulation (EU) 2018/848, if a bakery or a butchery produces, prepares, distributes or stores organic or in-conversion products, it must notify its activity to the competent authorities of its Member State and it will be subject to the control and certification system. Equally, pursuant to Article 34(2) of Regulation (EU) 2018/848, if a bakery or a butchery only sells prepacked organic products directly to the final consumer or user, it may be exempted from the certification provided that certain conditions are respected.

14) Can a food contact material made from organic agricultural ingredients be in the scope of the organic legislation?

It is important to distinguish between food contact materials sold as edible products and food contact materials that are not expected to be ingested by humans. The first type of food contact material, labelled as "can be eaten", may fall under the definition of food (Article 2 of Regulation (EC) No 178/2002: "...'*food*' ... means any substance or product,... intended to be, or reasonably expected to be ingested by humans. ..."). Food contact materials sold as edible products obtained by processing agricultural products are included in the scope of Regulation (EU) 2018/848 and can be labelled organic, provided that they satisfy the requirements set out in the legislation. Producers of such products can be certified organic in accordance with Regulation (EU) 2018/848.

The second type of food contact material, which is not produced with the intention of being sold as food, falls outside the scope of Regulation (EU) 2018/848 as it is not mentioned in Article 2 of the Regulation. It cannot therefore bear the EU organic logo which can only be used for products that comply with Regulation (EU) 2018/48. However, subject to a case-by-case analysis and the respect of Article 30 of Regulation (EU) 2018/848, the products at stake may bear terms referring to organic production in relation to their ingredients if they are produced from organic agricultural ingredients and if this labelling is not liable to mislead the consumer.

15) May hemp or Cannabis sativa plants be in the scope of the organic legislation?

Yes. Article 2 of Regulation (EU) 2018/848 lays down the scope of EU organic legislation, and refers to "*live or unprocessed agricultural products, including seeds*

and other plant reproductive material ", "processed agricultural products for use as food", and "feed".

Agricultural products are listed in Annex I to the Treaty of the Functioning of the European Union (TFEU) and true hemp (*Cannabis sativa*) is included. True hemp (*Cannabis sativa*) used for food or feed may therefore be certified as organic, provided that it complies with the rules on production and labelling set out in Regulation (EU) 2018/848. In addition, true hemp (*Cannabis sativa*) plants may require permission for cultivation for medical, scientific, industrial, or horticultural purposes. It is therefore important to contact the competent national authorities in the Member State in which the cultivation would occur to verify the specific conditions to be fulfilled.

16) Is it possible to certify organic mineral and spring water?

No. Mineral water and spring water are not included in the scope of Regulation (EU) 2018/848.

17) Is it possible to certify organic cork stoppers?

Yes. Cork stoppers are listed in Annex I to Regulation (EU) 2018/848 as *"cork stoppers of natural cork, not agglomerated, and without any binding substances"* and Regulation (EU) 2018/848 therefore applies to these products, when they are, or are intended to be, produced, prepared, labelled, distributed, placed on the market, imported into or exported from the Union.

The organic production rules for plant products laid down in Articles 9 to 12 of Regulation (EU) 2018/848 and Part I of Annex II to that Regulation apply to the production of cork oak, from which cork stoppers are produced. There are no detailed specific production rules for the organic production of *"cork stoppers of natural cork, not agglomerated, and without any binding substances"*. However, as for other organic products, relevant provisions of Union law apply: in particular Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food and, Regulation (EC) No 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food for this type of product.

In addition, as mentioned in the description of the products in Annex I of Regulation (EU) 2018/848, binding substances must not be used in the production of organic cork stoppers. In accordance with Article 21(2) of Regulation (EU) 2018/848, in the absence of detailed production rules, operators producing organically cork stoppers of natural cork, not agglomerated, and without any binding substances, *"shall (...) comply with the relevant principles laid down in Articles 5 and 6, mutatis mutandis with the principles laid down in Article 7, and with the general production rules laid down in Articles 9 to 11" (...) a Member State may, as regards products referred to*

in paragraph 1, apply detailed national production rules, provided that those rules are in accordance with this Regulation, and provided that they do not prohibit, restrict or impede the placing on the market of products which have been produced outside its territory and which comply with this Regulation."

As regards the use of products and substances, respect of the principles of organic production includes, for example, the following requirements of Regulation (EU) 2018/848:

- the production of these products responds to consumers' demand for goods that are produced by the use of processes that do not harm the environment and human health, plant health or animal health and welfare (Article 5(d));
- the restriction of the use of external inputs (Article 5(g));
- the restriction of the use of products and substances so that they are used to a minimum extent and only in cases of essential technological need (Article 7(b), *mutatis mutandis*);
- the exclusion of substances and processing methods that might be misleading as regards the true nature of the product (Article 7(c), *mutatis mutandis*); and
- the processing of the cork stoppers with care, preferably through the use of biological, mechanical and physical methods (Article 7(d), *mutatis mutandis*).

18) Is it possible to certify algal oil rich in DHA (docosahexaenoic acid) as organic food?

Yes, but under strict and limited conditions.

First, Article 2 of Regulation (EU) 2018/848 provides as follows: "*1. This Regulation applies to the following products originating from agriculture, including aquaculture and beekeeping, as listed in Annex I to the TFEU and to products originating from those products, where such products are, or are intended to be, produced, prepared, labelled, distributed, placed on the market, imported into or exported from the Union:*

(a) live or unprocessed agricultural products, including seeds and other plant reproductive material;

(b) processed agricultural products for use as food;

(c) feed.

This Regulation also applies to certain other products closely linked to agriculture listed in Annex I to this Regulation, where they are, or are intended to be, produced, prepared, labelled, distributed, placed on the market, imported into or exported from the Union."

Given that algae are included as agricultural products in Annex I (Chapter 12) to the TFEU, algal oil rich in DHA can therefore constitute an organic processed food when they originate from algae and are produced in accordance with Regulation (EU) 2018/848.

Second, DHA is a primary structural component of the brain, cerebral cortex, skin and retina. It is an essential fatty acid that the human body requires in tiny amounts⁴.

Third, DHA constitutes a “micronutrient” within the meaning of 2.2.2(f) of Part IV of Annex II to Regulation (EU) 2018/848. While the term “micronutrient” is not defined in any EU legislation, the glossary of the European Food Safety Authority defines a micronutrient as a “nutrient required by the body in tiny amounts for normal growth, development and maintenance of health; for example, vitamins and minerals”.

Fourth, as DHA is a micronutrient, its use in organic processed food is strictly limited, in accordance with point 2.2.2(f) of Part IV of Annex II to Regulation (EU) 2018/848:

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

(f) minerals (trace elements included), vitamins, amino acids and micronutrients, provided that:

(i) their use in food for normal consumption is 'directly legally required', in the meaning of being directly required by provisions of Union law or provisions of national law compatible with Union law, with the consequence that the food cannot be placed at all on the market as food for normal consumption if those minerals, vitamins, amino acids or micronutrients are not added; or

(ii) as regards food placed on the market as having particular characteristics or effects in relation to health or nutrition or in relation to needs of specific groups of consumers:

— in products referred to in points (a) and (b) of Article 1(1) of Regulation (EU) No 609/2013 of the European Parliament and of the Council (1) their use is authorised by that Regulation and acts adopted on the basis of Article 11(1) of that Regulation for the products concerned, or

— in products regulated by Commission Directive 2006/125/EC (2), their use is authorised by that Directive”.

19) Is it possible to certify Beeswax comb foundation sheets made of organic beeswax as organic?

Yes. First, Article 2 of Regulation (EU) 2018/848 extends the scope of the EU organic legislation to *“certain other products closely linked to agriculture listed in Annex I to this Regulation, where they are, or are intended to be, produced, prepared, labelled, distributed, placed on the market, imported into or exported from the Union.”*

⁴ <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2010.1734>

Second, Beeswax is listed in Annex I to Regulation (EU) 2018/848⁵ and hence Regulation (EU) 2018/848 applies where beeswax is - or is intended to be - produced, prepared, labelled, distributed, placed on the market, imported into or exported from the Union.

Beeswax can therefore be certified organic where it is - or is intended to be - produced, prepared, labelled, distributed, placed on the market, imported into or exported from the Union subject to the respect of all applicable provisions.

Third, the provisions of point 1.9.6.5 (e) of part II of Annex II to Regulation (EU) 2018/848 related to housing and husbandry practices for bees provide that:

"With regard to housing and husbandry practices, the following rules shall apply: (...) (e) the beeswax for new foundations shall come from organic production units;"

Beeswax comb foundation sheets are made up of beeswax which is heated to be shaped in the form of comb sheets. This heating and this shaping constitute a preparation, as defined in point (44) of Article 3 of Regulation (EU) 2018/848.

Given that beeswax comb foundation sheets made from organic beeswax can be considered as prepared beeswax, operators producing organic beeswax or preparing beeswax comb foundation sheets from organic beeswax may therefore be certified as organic, provided the products are produced in accordance with Regulation (EU) 2018/848.

20) Is it possible to certify additives and flavourings as organic?

Yes. First, Article 2 of Regulation (EU) 2018/848 provides as follows:

"1. This Regulation applies to the following products originating from agriculture, including aquaculture and beekeeping, as listed in Annex I to the TFEU and to products originating from those products, where such products are, or are intended to be, produced, prepared, labelled, distributed, placed on the market, imported into or exported from the Union:

(a) live or unprocessed agricultural products, including seeds and other plant reproductive material;

*(b) **processed agricultural products for use as food;***

(c) feed.

This Regulation also applies to certain other products closely linked to agriculture listed in Annex I to this Regulation, where they are, or are intended to be, produced,

⁵ In box 6 of Part I of the certificate of the operator, beeswax must therefore be referenced as belonging to "product category (g)" of Article 35(7) of Regulation 2018/848 (i.e. "other products listed in Annex I to Regulation 2018/848 or not covered by the previous categories listed in Article 35(7)). The certificate referred to in Article 35(1) of Regulation (EU) 2018/848 is issued by national authorities (or control authorities or control bodies), in accordance with the model set out in Annex VI to that Regulation. This document confirms that the activity of the operator complies with Regulation (EU) 2018/848.

prepared, labelled, distributed, placed on the market, imported into or exported from the Union."

Second, Article 3, point 45, of Regulation (EU) 2018/848, defines food by reference to Article 2 of Regulation (EC) No 178/2002: "*food includes any substance intended to be or reasonably expected to be ingested by humans*".

Additives and flavourings that are intended to be incorporated into food during its manufacture, preparation or treatment are therefore considered as food. Consequently, additives and flavourings originating from products listed in Annex I to the TFEU, including by processing, fall within the scope of Regulation (EU) 2018/848 and can be certified as organic, provided they are produced in accordance with Regulation (EU) 2018/848. A list of food additives which can be used in organic production is included in Commission Implementing Regulation (EU) 2021/1165.

21) Is it possible to certify prickly pear oil as organic?

Yes, but under strict conditions.

First, prickly pear is one of the common names⁶ for the fruit of *Opuntia ficus-indica*.

Second, both the edible fruit of *Opuntia ficus-indica* (L.) and the juice derived from the fruit and the platiclades of 'prickly pears' are considered under the Novel Food Regulation (EU) 2015/2283 as foods already used for human consumption ("not novel in food")⁷. However, the oil extracted from the seeds of *Opuntia ficus-indica* has not yet been assessed under the Novel Food Regulation. Article 4 of the Novel Food Regulation requires food business operators to verify whether the food they intend to place on the EU market falls within the scope of the Novel Food Regulation that is, whether the food is novel or not. If, after considering all the information available, food business operators are still unsure about whether a food is novel, they must consult the EU Member State where they first intend to place the food on the market. Commission Implementing Regulation (EU) 2018/456 lays down the information requirements that need to be included in the consultation request, including provisions on the confidentiality of the request, and the procedural steps business operators must follow for the consultation process. The possible certification of the product will therefore depend on the potential final use of this oil extracted from prickly pear seeds.

On the one hand, if the oil derived from *Opuntia ficus-indica* seeds is intended to be placed on the market as food, the oil must first be assessed under the Novel Food Regulation. It is only after this assessment, and if considered suitable for food and feed, that prickly pear seed oil may qualify as an organic processed agricultural

⁶. Other common names of this product are barbary fig, indian fig, indian fig opuntia.

⁷ [Food and Feed Information Portal Database | FIP \(europa.eu\)](#) According to the information available to the Member States' competent authorities, this product was used for human consumption to a significant degree within the Union before 15 May 1997. Thus, it is not considered to be 'novel' according to the provisions of the Novel Food Regulation (EU) 2015/2283 and its access to the market is not subject to the pre-market authorisation in accordance with Regulation (EU) 2015/2283. However, other legislation may restrict the placing on the market of this product as a food in the EU or in some Member States. Therefore, it is recommended to check with the competent authority(ies) of the Member State(s).

product under Regulation (EU) 2018/848, provided that this oil is produced in accordance with Regulation (EU) 2018/848.

On the other hand, if prickly pear seed oil is intended to be placed on the market as a cosmetic, it cannot be certified as organic. In general, it is neither possible to certify this product as organic when it has been labelled and placed on the market as a cosmetic product nor to display the organic production logo of the European Union on it because these products are not included in the scope of Regulation (EU) No 2018/848. Pursuant to Article 2 and Annex I of Regulation (EU) No 2018/848, that regulation applies only to: (i) unprocessed agricultural products and to processed products originating from agriculture, including aquaculture, which are intended for use as food or animal feed; and certain other products closely linked to agriculture listed in Annex I to this Regulation, where they are, or are intended to be, produced, prepared, labelled, distributed, placed on the market, imported into or exported from the Union.

22) Is it possible (1) to certify a product as organic, when it has been labelled and placed on the market as a cosmetic product and (2) to display the organic production logo of the European Union on it?

No, in general, it is neither possible to certify a product as organic when it has been labelled and placed on the market as a cosmetic product nor to display the organic production logo of the European Union on it because these products are not included in the scope of Regulation (EU) No 2018/848. Pursuant to Article 2 and Annex I of Regulation (EU) No 2018/848, that regulation applies only to: (i) unprocessed agricultural products and to processed products originating from agriculture, including aquaculture, which are intended for use as food or animal feed; and certain other products closely linked to agriculture listed in Annex I to this Regulation, where they are, or are intended to be, produced, prepared, labelled, distributed, placed on the market, imported into or exported from the Union.

Given essential oils are listed in Annex I to Regulation (EU) No 2018/848, they are within the scope of the EU organic legislation and these products may be certified as organic regardless of their final use, subject to the respect of all the applicable provisions. For example, essential oils used as cosmetic products are subject to the provisions of Regulation (EC) No 1223/2009 and, in particular, for labelling, they are subject to Article 20 of that regulation which lays down requirements on product claims (please see the reply to question 1.10).

Please see also the replies to questions 1.7 and 2.14.

23) Is it possible to certify argan oil or jojoba oil as organic for use as cosmetics?

No, in general, it is neither possible to certify a product as organic when it has been labelled and placed on the market as a cosmetic product nor to display the organic production logo of the European Union on it because these products are not included in the scope of Regulation (EU) No 2018/848. Pursuant to Article 2 and Annex I of Regulation (EU) No 2018/848, that regulation applies only to: (i) unprocessed

agricultural products and to processed products originating from agriculture, including aquaculture, which are intended for use as food or animal feed; and certain other products closely linked to agriculture listed in Annex I to this Regulation, where they are, or are intended to be, produced, prepared, labelled, distributed, placed on the market, imported into or exported from the Union.

If Argan oil or jojoba oil (which are vegetable oils obtained by pressing the kernels of the argan tree or seeds of jojoba) is intended to be placed on the market as food, they may qualify as organic processed agricultural products under Regulation (EU) 2018/848 provided that these oils are produced in accordance with Regulation (EU) 2018/848.

24) Is it possible to certify land snails as organic and if yes, what are the specific organic production rules to be applied?

Yes, land snails can be certified organic because: (i) they fall within the category “live agricultural products” within the meaning of Article 2 of Regulation (EU) 2018/848; and (ii) their production falls under the definition of livestock production within the meaning of Article 3, point (27), of that Regulation.

However, there are currently no organic rules for the production of land snails in Regulation (EU) 2018/848. In accordance with Article 21(2) of Regulation (EU) 2018/848, in the absence of these detailed production rules, operators producing organically land snails, *“shall, as regards products referred to in paragraph 1, comply with the principles laid down in Articles 5 and 6, mutatis mutandis with the principles laid down in Article 7, and with the general production rules laid down in Articles 9 to 11; (b) a Member State may, as regards products referred to in paragraph 1, apply detailed national production rules, provided that those rules are in accordance with this Regulation, and provided that they do not prohibit, restrict or impede the placing on the market of products which have been produced outside its territory and which comply with this Regulation.”*

25) Is it possible to certify maté as organic?

Yes. Maté is listed in Annex I to Regulation (EU) 2018/848⁸ and Regulation (EU) 2018/848 therefore applies to this product when it is, or is intended to be, produced, prepared, labelled, distributed, placed on the market, imported into or exported from the Union.

The organic production rules for plant products laid down in Articles 9 to 12 of Regulation (EU) 2018/848 and Part I of Annex II to that Regulation apply to the production of the leaves of *Ilex paraguariensis*, from which the traditional herbal infusion is produced. For the organic production of maté as herbal infusion, as for

⁸ In box 6 of Part I of the certificate of the operator, maté must therefore be referenced as belonging to “product category (g)” of Article 35(7) of Regulation 2018/848 (i.e. “other products listed in Annex I to Regulation 2018/848 or not covered by the previous categories listed in Article 35(7)). The certificate referred to in Article 35(1) of Regulation (EU) 2018/848 is issued by national authorities (or control authorities or control bodies), in accordance with the model set out in Annex VI to that Regulation. This document confirms that the activity of the operator complies with Regulation (EU) 2018/848.

other organic products, relevant provisions of Union law apply in particular Article 16 of Regulation (EU) 2018/848 on production rules for processed food.

26) *Is it possible to certify sweetcorn as organic?*

Yes. Sweetcorn is listed in Annex I to Regulation (EU) 2018/848⁹ and Regulation (EU) 2018/848 therefore applies to this product, when it is, or is intended to be, produced, prepared, labelled, distributed, placed on the market, imported into or exported from the Union.

The organic production rules for plant products laid down in Articles 9 to 12 of Regulation (EU) 2018/848 and Part I of Annex II to that Regulation apply to the production of sweetcorn to be placed on the market as raw material.

For sweetcorn placed on the market as a processed food product, as for other organic products, relevant provisions of Union law apply, in particular, Article 16 of Regulation (EU) 2018/848 on production rules for processed food.

27) *Is it possible to certify vine leaves as organic?*

Yes. Vine leaves are listed in Annex I to Regulation (EU) 2018/848¹⁰ and Regulation (EU) 2018/848 therefore applies to these products, when they are, or are intended to be, produced, prepared, labelled, distributed, placed on the market, imported into or exported from the Union.

The organic production rules for plant products laid down in Articles 9 to 12 of Regulation (EU) 2018/848 and Part I of Annex II to that Regulation apply to the production of vine leaves (the plants). for the organic production of the processed vine leaves, as for other organic products, relevant provisions of Union law apply, in particular Article 16 of Regulation (EU) 2018/848 on production rules for processed food.

28) *Is it possible to certify palm hearts as organic?*

⁹ In box 6 of Part I of the certificate of the operator, sweetcorn must therefore be referenced as belonging to “product category (g)” of Article 35(7) of Regulation 2018/848 (i.e. “other products listed in Annex I to Regulation 2018/848 or not covered by the previous categories listed in Article 35(7)). The certificate referred to in Article 35(1) of Regulation (EU) 2018/848 is issued by national authorities (or control authorities or control bodies), in accordance with the model set out in Annex VI to that Regulation. This document confirms that the activity of the operator complies with Regulation (EU) 2018/848.

¹⁰ In box 6 of Part I of the certificate of the operator, vine leaves must therefore be referenced as belonging to “product category (g)” of Article 35(7) of Regulation 2018/848 (i.e. “other products listed in Annex I to Regulation 2018/848 or not covered by the previous categories listed in Article 35(7)). The certificate referred to in Article 35(1) of Regulation (EU) 2018/848 is issued by national authorities (or control authorities or control bodies), in accordance with the model set out in Annex VI to that Regulation. This document confirms that the activity of the operator complies with Regulation (EU) 2018/848.

Yes. Palm hearts are listed in Annex I to Regulation (EU) 2018/848¹¹ and Regulation (EU) 2018/848 therefore applies to these products, when they are, or are intended to be, produced, prepared, labelled, distributed, placed on the market, imported into or exported from the Union.

The organic production rules for plant products laid down in Articles 9 to 12 of Regulation (EU) 2018/848 and Part I of Annex II to that Regulation apply to the production of palm hearts (plants). For the organic production of the processed palm hearts, as for other organic products, relevant provisions of Union law apply, in particular, Article 16 of Regulation (EU) 2018/848 on production rules for processed food.

29) *Is it possible to certify hop shoots as organic?*

Yes. Hop shoots are listed in Annex I to Regulation (EU) 2018/848¹² and Regulation (EU) 2018/848 therefore applies to these products, when they are, or are intended to be, produced, prepared, labelled, distributed, placed on the market, imported into or exported from the Union.

The organic production rules for plant products laid down in Articles 9 to 12 of Regulation (EU) 2018/848 and Part I of Annex II to that Regulation apply to the production of hop shoots (plants). For the organic production of the processed hop shoots, as for other organic products, relevant provisions of Union law apply, in particular, Article 16 of Regulation (EU) 2018/848 on production rules for processed food.

30) *Is it possible to certify natural gums and natural resins as organic?*

Yes. Natural gums and resins are listed in Annex I to Regulation (EU) 2018/848¹³ and Regulation (EU) 2018/848 therefore applies to these products, when they are, or are

¹¹ In box 6 of Part I of the certificate of the operator, palm hearts must therefore be referenced as belonging to “product category (g)” of Article 35(7) of Regulation 2018/848 (i.e. “other products listed in Annex I to Regulation 2018/848 or not covered by the previous categories listed in Article 35(7)). The certificate referred to in Article 35(1) of Regulation (EU) 2018/848 is issued by national authorities (or control authorities or control bodies), in accordance with the model set out in Annex VI to that Regulation. This document confirms that the activity of the operator complies with Regulation (EU) 2018/848.

¹² In box 6 of Part I of the certificate of the operator, hop shoots must therefore be referenced as belonging to “product category (g)” of Article 35(7) of Regulation 2018/848 (i.e. “other products listed in Annex I to Regulation 2018/848 or not covered by the previous categories listed in Article 35(7)). The certificate referred to in Article 35(1) of Regulation (EU) 2018/848 is issued by national authorities (or control authorities or control bodies), in accordance with the model set out in Annex VI to that Regulation. This document confirms that the activity of the operator complies with Regulation (EU) 2018/848.

¹³ In box 6 of Part I of the certificate of the operator, natural gums and resins must therefore be referenced as belonging to “product category (g)” of Article 35(7) of Regulation 2018/848 (i.e. “other products listed in Annex I to Regulation 2018/848 or not covered by the previous categories listed in Article 35(7)). The certificate referred to in Article 35(1) of Regulation (EU) 2018/848 is issued by national authorities (or control authorities or control bodies), in accordance with the model set out in Annex VI to that Regulation. This document confirms that the activity of the operator complies with Regulation (EU) 2018/848.

intended to be, produced, prepared, labelled, distributed, placed on the market, imported into or exported from the Union.

The organic production rules for plant products laid down in Articles 9 to 12 of Regulation (EU) 2018/848 and Part I of Annex II to that Regulation apply to the production of the plants from which natural gums and resins originate. There are no detailed specific production rules for the organic production of the processed natural gums and resins. However, as for other organic products, relevant provisions of Union law apply in particular Article 16 of Regulation (EU) 2018/848 on production rules for processed food.

In accordance with Article 21(2) of Regulation (EU) 2018/848, in the absence of detailed production rules, operators producing processed natural gums and resins, *"shall (...) comply with the relevant principles laid down in Articles 5 and 6, mutatis mutandis with the principles laid down in Article 7, and with the general production rules laid down in Articles 9 to 11" (...) a Member State may, as regards products referred to in paragraph 1, apply detailed national production rules, provided that those rules are in accordance with this Regulation, and provided that those rules are in accordance with this Regulation, and provided that they do not prohibit, restrict or impede the placing on the market of products which have been produced outside its territory and which comply with this Regulation"*.

31) Is it possible to certify pet food as organic?

Yes. Regulation (EU) 2018/848 lays down rules on organic production and labelling of organic products. That Regulation applies both to feed for food-producing animals and to feed for pets, namely pet food. Operators that produce organic pet food must comply, in particular, with Article 17 of Regulation (EU) 2018/848 and with the detailed production rules set out in Part V of Annex II of that Regulation and in Implementing Regulation (EU) 2021/1165.

Regulation (EU) 2023/2419 lays down specific labelling requirements for pet food produced in accordance with the rules concerning organic production of feed in Regulation (EU) 2018/848.

2. LABELLING AND LOGO

1) What does the organic logo of the European Union look like?

It is often named the “Euro-leaf”. It symbolizes the marriage of Europe (the stars derived from the European flag) and nature (the stylized leaf and the green color).

2) What is the meaning of the EU organic logo?

For processed products, the EU organic logo indicates that the product is in full conformity with the rules and conditions applicable to the production of processed food and that at least 95% of the ingredients of agricultural origin are organic. Next to the EU organic logo, a code number of the control body must be displayed as well as the place where the agricultural raw materials composing the product have been farmed.

3) What needs to be considered when using the EU organic logo?

The relevant EU legislation is Regulation (EU) No 2018/848. Moreover, the European Commission’s Directorate-General for Agriculture and Rural Development has developed a detailed user manual, which includes concrete guidelines for the use of the EU organic logo. The user manual is available for download on the EU Organic Farming Website at the following address:

https://agriculture.ec.europa.eu/farming/organic-farming/organic-logo_en#displayingthelogo

4) Is the use of the EU organic logo compulsory and if yes, can it coexist with other national and private labels?

Where the terms referred to in Article 30(1) of Regulation (EU) No 2018/848 are used (e.g. organic, bio, eco...), the EU organic logo is compulsory for the labelling and advertising of organic prepackaged food products, which satisfy the requirements of the EU organic legislation, in particular see Article 32(1), point (b).

In compliance with Article 33(5), national and private logos can also be used and displayed on products which comply with the same Regulation.

5) For which products is the EU organic logo not to be used?

The EU organic logo cannot be used for products which are not covered by the scope of the EU organic legislation or that do not satisfy the requirements set out under Regulation (EU) No 2018/848. The EU organic logo shall not be used in the case of in-conversion products and processed food as referred to in Article 30(5), points (b) and (c), of Regulation (EU) No 2018/848, i.e. products containing less than 95% of organic ingredients or containing mainly products of hunting and fishing of wild animals.

Examples of use:

Can the EU organic logo be used on packaging material of the following products on condition that they satisfy the requirements set out under Regulation (EU) No 2018/848?

- Sardines in organic olive oil: NO
- Organic farming salmon: YES
- Organic wine: YES
- Soup made from organic vegetables: YES
- Wool from organic sheep: YES
- Milk from a dairy farm in conversion period: NO

6) What additional information is mandatory when the EU organic logo is used?

Whenever the EU organic logo is used on a product, it always has to be accompanied by the code number of the control body and the place where the agricultural raw materials of which the product is composed have been farmed.

7) Where should the mandatory additional information be placed?

The code number of the control body or control authority shall be placed in the same visual field as the EU organic logo. Indication of the place of farming should appear directly below the reference to the control body. You can find at the following address further information including a user manual:

https://agriculture.ec.europa.eu/farming/organic-farming/organic-logo_en

8) How should the code number of the control body be displayed?

The code number shall appear as follows: AB-CDE-999 where "AB" is the ISO code for the country where the controls take place, "CDE" is a term establishing a link with the organic production like "bio" or "eko" and "999" is the attributed reference number composed of 1 to 3 digits.

9) How should the indication of origin place of farming be displayed?

The indication of the place where the agricultural raw materials of which the product is composed have been farmed shall appear as follows:

- 'EU Agriculture', where the agricultural raw material has been farmed in the EU;
- 'non-EU Agriculture', where the agricultural raw material has been farmed in third countries;
- 'EU/non-EU Agriculture', where part of the agricultural raw materials has been farmed in the Union and part has been farmed in a third country. The indication 'EU' or 'non-EU' can be replaced or supplemented by a country where all agricultural raw materials of which the product is composed have been farmed in that country. For the above-mentioned 'EU' or 'non-EU' indication, small quantities by weight of ingredients can be disregarded provided that the total quantity of the disregarded ingredients does not exceed 5% of the total quantity by weight of raw materials of agricultural origin.

10) Is it compulsory to indicate the code number of the control body and the place of farming on the labelling of products where the EU organic logo is not used?

Yes. The code number of the control body must appear on all products using the terms referring to organic production, irrespective of the use of the EU organic logo. However, the place of farming is compulsory only when the logo is used.

11) Is there a database or catalogue of companies producing organic certified products available on the Europa website?

Not yet. However a list of approved control bodies and control authorities in charge of controls is available on the EU organic website. These control bodies can be distinguished by the code number that is displayed under the EU organic logo. By visiting the websites of these approved control bodies and control authorities, you

can access a list of operators and the products that they produce and which are certified as organic.

EU organic website:

https://ec.europa.eu/agriculture/ofis_public/index.html

12) What are the technical aspects of placing the logo on the packaging?

For the technical aspects, please consult the user manual of the EU organic logo.

https://agriculture.ec.europa.eu/farming/organic-farming/organic-logo_en

13) Can I reduce the size of the logo for very small packages?

Annex V of Regulation (EU) No 2018/848 establishes the model of the EU organic logo. In particular, point 1.7 establishes that "the organic logo of the EU must have a height of at least 9 mm and a width of at least 13,5 mm; the proportion ratio height/width shall always be 1:1,5. Exceptionally the minimum size may be reduced to a height of 6 mm for 'very small packages.'"

The concept of "very small packages" is not defined in Regulation (EU) No 2018/848. However, Article 13(6) of Regulation (EC) No 1169/2011 on food information for consumers allows for the omission of certain mandatory food information *"in the case of packaging or containers the largest surface of which has an area of less than 10 cm²"*. Therefore, if, in view of the labelling requirements laid down in the above-mentioned Regulations it can be considered that the package is too small to be labelled with these labelling requirements and retain the integrity of the EU organic logo at the minimum size of 9mm/13.5mm, the logo can be reduced, exceptionally, to a height of 6mm.

A downloadable EU organic logo user manual is available on the DG AGRI organic website with all relevant technical details:

https://agriculture.ec.europa.eu/farming/organic-farming/organic-logo_en#when-to-use-the-organic-logo

14) Can I use the EU organic logo in a brochure concerning cosmetic products?

No. The scope of the EU organic legislation is set out in Article 2 of Regulation (EU) No 2018/848. Processed agricultural products not intended for use as food (i.e. cosmetic products) are not covered by the scope of the EU organic legislation. As a consequence, they can neither be certified as organic, nor labelled or advertised using the EU organic logo. The production and labelling of organic cosmetics is not regulated at EU level.

15) Does the list of ingredients have to indicate which ingredients are organic?

Yes. The list of ingredients shall indicate which ingredients are organic as set out in Article 30(5) of Regulation (EU) No 2018/848. The list of ingredients of processed food must indicate which ingredients are organic even if they are all organic.

16) Is the use of a third country organic label for products imported to EU sufficient or is the product required to bear also the EU organic label?

Article 33(3) of Regulation (EU) 2018/848 states that the use of the EU organic logo for products imported from third countries shall be optional: *"The use of the organic production logo of the European Union shall be optional for products imported from third countries. Where the logo appears in the labelling of such products, the indication referred to in Article 32(2) shall also appear in the labelling"*. Therefore, in accordance with the above, the use of the third country organic certified label is sufficient, and the use of the EU organic logo is optional.

However, it must be recalled that a product may be imported from a third country to be placed on the market in the EU only when complying with all the conditions laid down under Article 45 of Regulation (EU) 2018/848.

17) Can I use the EU organic logo in my restaurant menu?

No. The rules on organic production and the use of the EU organic logo in the labelling, presentation and advertising of products which are placed on the market in the EU as organic are set out in Regulation (EU) No 2018/848. The scope of the Regulation is set out in its Article 2. According to the second subparagraph of Article 2(3), Member States can apply national rules, or in the absence thereof, private

standards, on the production, labelling and control of products originating from mass catering operations. The organic production logo of the European Union shall not be used in the labelling, the presentation or the advertising of such products, and shall not be used to advertise the mass caterer.

18) What compulsory indications should appear in the labelling of unpackaged organic products?

Pursuant to Article 32 of Regulation (EU) No 2018/848, the code number of the control body or control authority is a compulsory requirement for products which bear terms referring to organic. Thus, the code number of control bodies must appear on all organic products, whether the EU organic logo is used or not. Where the logo is used, the place of farming of the agricultural raw material is also compulsory. These indications are to be labelled in accordance with Article 32 in the sense that they shall be "marked in a conspicuous place in such a way as to be easily visible, clearly legible and indelible".

19) Can I use the EU organic logo in black and white, and can it be used in sticker form?

Article 33(4) of Regulation (EU) No 2018/848 states that *"the organic production logo of the EU shall follow the model set out in Annex V, and shall comply with the rules set out in that Annex"*. Moreover, under point 1.3 of that Annex V: *"the organic production logo of the EU may also be used in black and white as shown only where it is not practicable to apply it in colour"*. As outlined in Articles 32 and 33 of Regulation (EU) No 2018/848, whenever the EU organic logo is used on a product, it has to appear together with other obligatory labelling requirements. Thus a sticker placed on a product showing the logo alone - without the obligatory labelling requirements – is not deemed to comply with the EU organic legislation.

20) Can a citizen use and publish the EU organic logo in a publication or on a website?

Use of the EU organic logo in the labelling, presentation and advertising of products which are placed on the market in the EU as organic is regulated by Regulation (EU) No 2018/848. Article 33 of that Regulation lays down that the EU organic logo may also be used for information and educational purposes related to the existence and advertising of the logo itself, provided that such use is not liable to mislead the consumer as regards the organic production of specific products, and provided that

the logo is reproduced in accordance with the rules set out in Annex V of that regulation.

21) Is it possible to label on the front of a packaging of a processed food "the product has an organic ingredient"?

In accordance with Article 30(5) a product with less than 95% of its agricultural ingredients as organic cannot use the term organic on the front of the packaging but can indicate which ingredients are organic in the list of ingredients. Article 30(5)(b) specifically provides that for processed food, the terms referring to the organic production method such as "organic", can be used *"only in the list of ingredients provided that (i) less than 95% of the agricultural ingredients of the product by weight are organic, and provided that those ingredients comply with the production rules set out in this Regulation and (ii) the processed food complies with the production rules set out in points 1.5, 2.1(1), 2.1(b) and 2.2.1 of Part IV of Annex II and with exception of rules on restricted use of non-organic agricultural ingredients set out in point 2.2.1 of Part IV of Annex II and with the rules laid down in accordance with Article 16(3)".*

This is the case when processed food contains organic ingredients together with non-organic ingredients. In such cases:

"The list of ingredients referred to in points (a), (b) and (c) of the first subparagraph shall indicate which ingredients are organic. The references to organic production may only appear in relation to the organic ingredients. The list of ingredients referred to in point (b) and (c) of the first subparagraph shall include an indication of the total percentage of organic ingredients in proportion to the total quantity of agricultural ingredients. The terms referred to in paragraph 1, when used in the list of ingredients referred to in point (a), (b) and (c) of the first subparagraph of this paragraph shall appear in the same colour, identical size and style of lettering as the other indications in the list of ingredients".

22) Is the EU organic logo required on the packaging and delivery note received from a European supplier (Business to business) for organic raw material?

According to Article 30 of Regulation (EU) 2018/848 a product is regarded *"as bearing terms referring to the organic production method where, in the labelling, advertising material or commercial documents such a product, its ingredients or feed materials used for its production are described in terms suggesting to the purchaser that the product, ingredients or feed materials have been produced in accordance with this Regulation. In particular the terms listed in Annex IV and their derivatives and diminutives, such as "bio" and "eco" whether alone or in combination, may be*

used throughout the Union and in any language listed in that Annex for the labelling and advertising of products referred to in Article 2(1) which comply with this Regulation."

In accordance with Article 32 of the same Regulation, where such terms appear, it is compulsory to indicate, in the labelling, the code number of the control body / control authority to which the operator who has carried out the most recent production or preparation operation is subject. Article 32(1), point (b), in particular provides that the use of the EU organic logo is compulsory only for organic pre-packaged food when produced within the European Union and when compliant, among others, with the requirement in Article 30 that at least 95% of the agricultural ingredients of the product are by weight organic.

Thus, when reference is made to the organic production method in the packaging of a product not intended for final consumption or the documentation accompanying the organic raw material is delivered business-to-business, the packaging and the commercial documents must bear the code number of the relevant control body, but are not required to use the EU organic logo.

23) Can an organic fig (being 75% of the whole product) covered with non-organic chocolate (25% of whole product) be labelled "Organic"?

No. The product does not comply with Article 30(5), point (a), of Regulation (EU) No 2018/848, which states that *"at least 95% of its ingredients of agricultural origin are organic"*.

However, in accordance with Article 30(5), point (b), of Regulation (EU) No 2018/848 the term *"organic"* can be used in the list of ingredients provided that the food complies with the production rules set out in points 1.5, 2.1(a), 2.1.(b) and 2.2.1. of Part IV of Annex II of that regulation, with the exception of rules on restricted use of non-organic agricultural ingredients set out in point 2.2.1.

When the term *"organic"* appears only in the list of ingredients, Article 30(5) of Regulation (EU) No 2018/848 also requires that: *"The list of ingredients referred to in points (a) (b) and (c) of the first subparagraph shall indicate which ingredients are organic. The references to organic production may only appear in relation to the organic ingredients. The list of ingredients referred to in points (b) and (c) of the first subparagraph shall include an indication of the total percentage of organic ingredients in proportion to the total quantity of agricultural ingredients"*.

24) Can terms referring to organic production be used in the sales description of processed food containing a product of hunting or fishing as its main ingredient?

Yes, but only under certain conditions. This follows from the specific nature of the products of hunting or fishing of wild animals, which pursuant to Article 3(2) of Regulation (EU) 2018/848, cannot be considered as organic products.

Article 30(5), point (c), of Regulation (EU) 2018/848 provides for the possibility of using the terms referring to organic production in the sales description of a product when the main ingredient is a product of hunting or fishing under specific conditions. In particular, point (ii) of that provision requires the term referring to organic production in the sales description to be clearly related to the organic ingredient and not to the product of hunting and fishing (e.g: tuna fish in organic olive oil).

25) Can the EU organic logo be applied on a music album cover?

No. The use of the organic production logo of the European Union in the labelling, presentation, and advertising of products, which are placed on the EU market as organic, is governed by Regulation (EU) 2018/848. The use of the organic production logo of the European Union is also subject to general rules on consumer protection and on the use of registered trademarks.

That logo is a registered trademark (registration number 018055852) owned by the EU. It cannot be used in a manner to mislead the public or to create the false impression that the music was sponsored or approved by the EU.

26) Can the EU organic logo be reproduced in the context of a Museum exhibition on coffee?

Yes. The use of the EU organic production logo in the labelling, presentation and advertising of organic products is governed by Regulation (EU) 2018/848. Article 33 of that regulation provides that the EU organic production logo may also be used for information and educational purposes related to the existence and advertising of the logo itself, provided that such use is not liable to mislead the consumer as regards the organic production of specific products, and provided that the logo is reproduced in accordance with the rules set out in Annex V of that Regulation.

On this basis, the EU organic logo can be reproduced for educational purposes in a museum exhibition.

27) Can the EU logo be used for educational purposes in a textbook or accompanying teaching material in digital format?

Yes. The use of the EU organic production logo in the labelling, presentation and advertising of products which are placed on the EU market as organic is governed by Article 33 of Regulation (EU) 2018/848, which states that the organic production logo may also be used for information and educational purposes related to the existence and advertising of the logo itself, provided that such use is not liable to mislead the consumer as regards the organic production of specific products, and provided that the logo is reproduced in accordance with the rules set out in Annex V of that Regulation.

28) Can a national organic logo which limits its use to operators acting in a specific country or using raw material from that specific country be in line with EU law?

Yes, but under strict conditions.

Article 33(5) of Regulation (EU) 2018/848 provides as follows: *"national logos and private logos may be used in the labelling, presentation and advertising of products which comply with this Regulation"*.

It is therefore the prerogative of each Member State to establish specific rules for the use of their national organic production logo, provided that the products comply with Regulation (EU) 2018/848 and the delegated and implementing acts adopted on the basis of that Regulation.

29) Is it possible to export organic products certified under Regulation (EU) 2018/848 and correctly labelled in compliance with that Regulation but without the EU logo?

Yes.

Article 32(1)(b) of Regulation (EU) 2018/848 provides for the compulsory indication of the EU organic production logo only in certain circumstances:

'Where products bear terms as referred to in Article 30(1), including products labelled as in-conversion products in accordance with Article 30(3):

(a) ...

(b) in the case of prepacked food, the organic production logo of the European Union referred to in Article 33 shall also appear on the packaging, except in cases referred to in Article 30(3) and points (b) and (c) of Article 30(5).'

By contrast, for the export of organic products, Article 44(1) of Regulation (EU) 2018/848 provides as follows:

'A product may be exported from the Union as an organic product and may bear the organic production logo of the European Union, provided that it complies with the rules for organic production under this Regulation.'

An operator exporting organic products that do not bear the EU organic production logo can comply with Regulation (EU) 2018/848 and consequently can be certified provided there is compliance with Regulation (EU) 2018/848.

30) How should organic pet food be labelled in compliance with Regulation (EU) 2018/848?

Pet food is feed for a specific category of animals, pets; the provisions of Regulation (EU) 2018/848 which apply to feed are therefore applicable to pet food, in particular those on production, certification, control, marketing, and trade with third countries. Article 2 of Regulation (EU) 2023/2419 states that *pet food means feed within the meaning of Article 3, point (46), of Regulation (EU) 2018/848 which is intended for pets as defined in Article 3(2), point (f), of Regulation (EC) No 767/2009*

Considering that pet food is mainly sold at retail level to the final consumers, Regulation (EU) 2023/2419 lays down specific requirements for the use of terms referring to organic production and for the use of the EU organic production logo on the labelling of organic pet food.

Please also see above (question/answer number 16 on the certification of organic pet food).

31) Which indication of the organic ingredients must be reported in the list of ingredients of an organic processed food in the case of a single ingredient product?

For food consisting of a single ingredient product, Article 19(1), point (e) of Regulation (EU) No 1169/2011 is relevant and states the following: *'Article 19 Omission of the list of ingredients 1. The following foods shall not be required to bear a list of ingredients: (...) (e) foods consisting of a single ingredient, where: (i) the name of the food is identical to the ingredient name; or (ii) the name of the food enables the nature of the ingredient to be clearly identified.'*

When the list of ingredients is not required, the provisions of Article 30(5) of Regulation (EU) 2018/848 on how to establish this list cannot therefore be applied. However, for the sales description, please note that relevant provisions of Regulation (EU) 2018/848 apply, in particular its Article 30 on the use of the terms referring to organic production.

Moreover, where the organic production logo of the European Union is used on these foods that are not required to bear a list of ingredients, Article 32(2) of Regulation (EU) 2018/848 requires an indication of the place where the agricultural raw materials of which the product is composed have been farmed. This indication must appear in the same visual field as the logo and must take one of the following forms, as appropriate: 'EU Agriculture', 'Non-EU Agriculture' or 'EU/Non-EU Agriculture'.

Consequently, if the place of farming of a single ingredient product is indicated as 'EU/Non-EU Agriculture', this means that some of the agricultural raw materials have been farmed in the Union and the other agricultural raw materials have been farmed in a third country. When the agricultural raw materials are from the same place, the indication of the place of farming must be 'EU agriculture' or 'Non-EU Agriculture' as appropriate.

On these issues, please see the replies to questions 9 and 15 above.

32) Which indication should be made in the list of ingredients of an organic food for organic compound ingredients?

All ingredients that are organic - including organic compound ingredients - must therefore be indicated as organic in the list of ingredients.

This flows from a combined reading of Article 30(5) of Regulation (EU) 2018/848, Article 3(51) of Regulation (EU) 2018/848 and point (f) of Article 2(2) of Regulation (EU) 1169/2011.

Article 30(5) of Regulation (EU) 2018/848 reads as follows: *'The list of ingredients referred to in points (a), (b) and (c) of the first subparagraph shall indicate which ingredients are organic. The references to organic production may only appear in relation to the organic ingredients.'*

The definition of ingredient is set out in Article 3(51) of Regulation (EU) 2018/848 as follows: *'ingredient means an ingredient as defined in point (f) of Article 2(2) of Regulation (EU) 1169/2021 or for products other than food, any substance or product used in the manufacture or preparation of products that is still present in the finished product even in altered form.'*

Point (f) of Article 2(2) of Regulation (EU) 1169/2011 reads as follows: *'(f) ingredient' means any substance or product, including flavourings, food additives and food enzymes, and any constituent of a compound ingredient, used in the manufacture or preparation of a food and still present in the finished product, even if in an altered form; residues shall not be considered as 'ingredients'.*

33) Can unpacked laser-labelled organic products be stored together with non-organic products at the same point of sale?

No. These organic products must be stored separately from the other agricultural products or foodstuffs. Point 7 of Annex III to Regulation (EU) 2018/848 is relevant and provides as follows:

' 7. Storage of products

7.1. Areas for the storage of products shall be managed in such a way as to ensure identification of lots and to avoid any mixing or contamination with products or substances not in compliance with the organic production rules. Organic and in-conversion products shall be clearly identifiable at all times.

7.2. No input products or substances other than those authorised pursuant to Articles 9 and 24 for use in organic production shall be stored in organic or in-conversion plant and livestock production units. [...]

7.4. Where operators handle organic, or in-conversion or non-organic products in any combination and the organic or in-conversion products are stored in storage facilities in which also other agricultural products or foodstuffs are stored;

(a) the organic or in-conversion products shall be kept separate from the other agricultural products or foodstuffs;

(b) every measure shall be taken to ensure identification of consignments and to avoid mixtures or exchanges between organic, in-conversion and non-organic products;

(c) suitable cleaning measures, the effectiveness of which has been checked, shall have been carried out before the storage of organic or in-conversion products and the operators shall keep records of those operations.

7.5. Only the products for cleaning and disinfection authorised pursuant to Article 24 for use in organic production shall be used in storage facilities for that purpose.'

Moreover, Article 38(1), point (c), of Regulation (EU) 2018/848 is also relevant and reads as follows:

'where organic, in-conversion and non-organic products are collected simultaneously by operators, are prepared or stored in the same preparation unit, area or premises, or are transported to other operators or units, the verification of the records and of the measures, procedures or arrangements in place to ensure that operations are carried out separated by place or time, that suitable cleaning measures and, where appropriate, measures to prevent substitution of products are implemented, that organic products and in-conversion products are identified at all times and that organic, in-conversion and non-organic

products are stored, before and after the preparation operations, separated by place or time from each other;’.

34) Can water-based drinks containing organic agricultural ingredient(s) be considered and labelled as organic even if mainly constituted of water?

Yes, under certain conditions.

First, Article 2 of Regulation (EU) 2018/848 provides as follows:

“This Regulation applies to the following products originating from agriculture, including aquaculture and beekeeping as listed in Annex I to the TFEU and to products originating from those products, where such products are, or are intended to be produced, prepared, labelled, distributed, placed on the market, imported into or exported from the Union: (a) live or unprocessed agricultural products, including seeds and other plant reproductive material; (b) processed agricultural products for use as food; (c) feed.

This regulation also applies to certain other products closely linked to agriculture listed in Annex I to this Regulation, where they are, or are intended to be, produced, prepared, labelled, distributed, placed on the market, imported into or exported from the Union.”

Agricultural ingredients which are listed in Annex I to the TFEU (for example, coffee, tea) or agricultural ingredients which are processed agricultural products for use as food (for example, flavouring, extract) as well as products listed in Annex I to Regulation (EU) 2018/848 (for example, maté, plant-based traditional herbal preparations) therefore fall within the scope of Regulation (EU) 2018/848.

Second, point 2.1(a) of Part IV of Annex II to Regulation (EU) 2018/848 provides that:

“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”.

Water-based drinks made of water and organic agricultural ingredients, or made of water and organic processed agricultural products intended for use as food, or made of water and products listed in Annex I to Regulation (EU) 2018/848, may therefore be considered as processed organic food and labelled as organic if all the applicable provisions are respected, in particular the production rules for processed organic food and the labelling rules.

35) Is the use of the EU organic logo allowed for water-based drinks?

Yes, under certain conditions.

Water-based drinks which are identified as organic food processed products may be labelled with terms referring to organic production in the sales description when at least 95% of the agricultural ingredients are organic (Article 30(5)(a) of Regulation (EU) 2018/848) and when the product complies with all the applicable rules. The organic production logo of the European Union may be used in the labelling of these products if the whole product complies with Regulation (EU) 2018/848.

However, in accordance with Article 30(2) of Regulation (EU) 2018/848, the EU organic logo and the terms referring to organic production must not be used in the labelling if they are liable to mislead the consumer or user by suggesting that water present in this product complies with this Regulation.

36) Can products produced during the conversion period be labelled or advertised as in-conversion products?

No, in principle, products that have been produced during the conversion period must not be labelled or advertised as organic products or as in-conversion products in accordance with the first subparagraph of Article 30(3) of Regulation (EU) 2018/848.

However, the second subparagraph of Article 30(3) provided for the following exception: *“plant reproductive material, food products of plant origin and feed products of plant origin that have been produced during the conversion period, which comply with Article 10(4) [of Regulation (EU) 2018/848], may be labelled and advertised as in-conversion products by using the term ‘in-conversion’ or a corresponding term, together with the terms referred to in paragraph 1.”*

In order to comply with Article 10(4) of Regulation (EU) 2018/848, food products of plant origin must contain *“only one agricultural crop ingredient”* and comply with a *“a conversion period of at least 12 months before the harvest.”*

Article 10(4) thus covers food products of plant origin such as wheat seeds, orange juice made only from oranges, non-enriched wine, cider made only from apples and soybean meal because those products are all composed of only one agricultural crop ingredient.

By contrast, Article 10(4) does not cover products of plant origin such as a mixture of fodder plant seeds, apple and mango juice, wine enriched with sugar and cider made from apples and pears or sugar because those products are all composed of more than one agricultural crop ingredient.

3. CERTIFICATION SYSTEM

1) Does an operator selling organic products via the internet (i.e. an internet online platform) need to get an "organic certification", or is it equivalent to selling products in a shop?

Yes, the operator needs to get an organic certification because the internet platform cannot be considered as "storage in connection with the point of sale". Regulation (EU) 2018/848 establishes the rules on organic production and labelling of organic products. Article 34(1) of that Regulation provides that "prior to placing any products on the market as "organic" or as "in-conversion" or prior to the conversion periods, operators and groups of operators referred to in Article 36 which [...] store [...] or which place such products on the market shall notify their activity to the competent authorities of the Member State in which it is carried out and in which their undertaking is subject to the control system."

In addition, Article 34(3) of Regulation (EU) 2018/848 provides that "where operators or groups of operators subcontract any of their activities to third parties, both the operator and groups of operators and the third parties shall comply with paragraph 1, unless the operator or group of operators has declared in the notification referred to in paragraph 1 that it remains responsible as regards organic production and that it has not transferred that responsibility to the sub-contractor. In such cases, the competent authority or where appropriate, the control authority or control body shall verify that the subcontracted activities comply with this Regulation in the context of the control it carries out on the operators or groups of operators that have subcontracted their activities."

This means that an internet commercial platform, even when the distribution or the "placing of the product on the market" has been subcontracted, must adhere to the organic certification system.

In addition, Article 34(2) of Regulation (EU) 2018/848 provides that "Operators that sell prepacked organic products directly to the final consumer or user shall be exempted from the notification obligation referred to in paragraph 1 of this Article and from the obligation to be in the possession of a certificate referred to in Article 35(2) provided they do not [...] store other than in connection with the point of sale [...]". In order for products to be sold 'directly to the final consumer at the point of sale' within the meaning of Article 35(2) it is necessary for the sale to occur in the presence of both the operator or its sales personnel and the final consumer. In the

case of internet sales, the products are stored at the point of dispatch, but there is a phase between storage and delivery to the final consumer (i.e. by mail).

In addition, the storage of organic products is subject to certain requirements as outlined in Annex III to Regulation (EU) 2018/848. The operator who has physical possession of the organic product during storage is required to submit its undertaking to the organic control system as outlined above. On this matter, considering the similarity of Article 28(2) of Regulation (EC) 834/2007 and Article 34(2) of Regulation (EU) 2018/848, it has to be kept in mind the Judgment of the Court of Justice in case C-289/16 concerning the interpretation of the analogous provisions laid down in Article 28(2) of Regulation (EC) No 834/2007 publicly available here:

<http://curia.europa.eu/juris/liste.jsf?num=C-289/16>

"Article 28(2) of Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91 must be interpreted as meaning that, in order for products to be regarded as being sold 'directly', within the meaning of that provision, to the final consumer or user, it is necessary for the sale to occur in the presence of both the operator or his sales personnel and the final consumer." This confirms an internet platform cannot be exempted from organic certification because the sale of the product does not occur in presence of both operators.

2) Can an internet platform be exempted from the organic control system when dealing with prepacked organic products, which will not undergo any modifications and are ready for the final consumer?

No, the distributor subcontracting the selling of organic products via the Internet is required to adhere to the organic certification system.

Regulation (EU) 2018/848 establishes the rules on organic production and labelling of organic products. Article 34(1) of that Regulation provides that "prior to placing any products on the market as "organic" or as "in-conversion" or prior to the conversion periods, operators and groups of operators referred to in Article 36 which [...] store [...] or which place such products on the market shall notify their activity to the competent authorities of the Member State in which it is carried out and in which their undertaking is subject to the control system."

In addition, Article 34(3) of Regulation (EU) 2018/848 provides that "where operators or groups of operators subcontract any of their activities to third parties, both the operator and groups of operators and the third parties shall comply with paragraph 1, unless the operator or group of operators has declared in the

notification referred to in paragraph 1 that it remains responsible as regards organic production and that it has not transferred that responsibility to the sub-contractor. In such cases, the competent authority or where appropriate, the control authority or control body shall verify that the subcontracted activities comply with this Regulation in the context of the control it carries out on the operators or groups of operators that have subcontracted their activities."

In addition, Article 34(2) of Regulation (EU) 2018/848 states that "Operators that sell prepacked organic products directly to the final consumer or user shall be exempted from the notification obligation referred to in paragraph 1 of this Article and from the obligation to be in the possession of a certificate referred to in Article 35(2) provided they do not [...] store other than in connection with the point of sale [...]".

In order for products to be sold 'directly to the final consumer at the point of sale' within the meaning of Article 35(2) of Regulation (EU) 2018/848, it is necessary for the sale to occur in the presence of both the operator or its sales personnel and the final consumer. In the case of internet sales, the products are stored at the point of dispatch, but there is a phase between storage and delivery to the final consumer (i.e. by mail). Thus, an internet platform cannot be considered as "storage in connection with the point of sale".

In addition, the storage of organic products is subject to certain requirements as outlined in Annex III to Regulation (EU) 2018/848. The operator who has physical possession of the organic product during storage is required to submit its undertaking to the organic control system as outlined above.

3) Can a citizen buy herbs from a certified organic business and then on his own package and label them in plant-based capsules and later sell the packaged product with an EU organic labelling and logo?

No, a product using terms referring to organic production must adhere to Regulation (EU) 2018/848 which establishes the rules on organic production and labelling of organic products.

Article 32 of that Regulation provides that it is compulsory to indicate "(a) *the code number of the control authority or control body to which the operator that carried out the last production or preparation operation is subject shall also appear in the labelling and (b) in the case of pre-packed food, the organic production logo of the European Union referred to in Article 33 shall also appear on the packaging, except in cases referred to in Article 30(3) and points (b) and (c) of Article 30(5).*"

Article 34(1) of that Regulation further provides that "prior to placing any products on the market as "organic" or as "in-conversion" or prior to the conversion periods, operators and groups of operators referred to in Article 36 which produce, prepare,

distribute [...] or which place such products on the market shall notify their activity to the competent authorities of the Member State in which it is carried out and in which their undertaking is subject to the control system.”

This means that the operator who has carried out the most recent preparation of the product – for packaging, labelling or alteration of the labelling – must submit the undertaking to the relevant control body/competent authority where the activity is carried out before placing the product on the market, and the code number of this control body/competent authority must appear on the packaging when in compliance with above-mentioned provisions.

4) How can a small producer of organic honey be allowed to use the EU organic certification and which will be the cost?

Regulation (EU) 2018/848 establishes the rules on organic production and labelling of organic products. Operators must adhere to the organic control system, which requires notifying the activity to the competent authorities and submitting the undertaking to the control system in accordance with Article 34 of Regulation (EU) 2018/848.

Regarding the cost of organic certification, Article 37(7) of Regulation (EU) 2018/848 provides that *“Member States shall ensure that any operator or group of operators that complies with this Regulation and, in cases where a fee is collected in accordance with Articles 78 and 80 of Regulation (EU) 2017/625, that pays a reasonable fee covering the cost of controls is entitled to be covered by the control system. Member States shall ensure that any fees that may be collected are made public.”*

In addition, specific provisions are laid down in Article 36 of Regulation (EU) 2018/848 to allow systems of group certification for operators to reduce the certification costs and the associated administrative burden.

5) Can EU organic products be sold via Internet and how?

Yes. Regulation (EU) 2018/848 establishes the rules on organic production and labelling of organic products. All organic production products using terms referring to organic production must adhere to this regulation. Article 32 of that regulation establishes the required compulsory labelling indications and Article 33 the requirements for the use of the EU organic logo.

Operators selling organic products must adhere to the organic certification system in accordance with Article 34 of Regulation (EU) 2018/848:

“Prior to placing any products on the market as organic or as in-conversion or prior to the conversion period, operators and group of operators referred to in Article 36 which produce, prepare, distribute, or store organic or in-conversion products, which import such products from a third country or export such products to a third country, or which place such products on the market, shall notify their activity to the

competent authorities of the Member State in which it is carried out and in which their undertaking is subject to the control system."

Regulation (EU) 2018/848 does not provide for rules concerning the use of the EU organic logo in contexts other than products placed on the market as organic. Therefore, the EU organic logo can be used on the product itself if it meets the requirements of Regulation (EU) 2018/848. If the EU organic logo is used on the e-commerce website, it can be done provided that the logo is presented in connection with a specific product and it is displayed together with the mandatory indications required by the EU organic legislation.

If terms referring to organic production are used on the website, the second paragraph of Article 30(2) of Regulation (EU) 2018/848 must be respected: "For the products referred to in Article 2(1), the terms referred to in paragraph 1 of this Article shall not be used anywhere in the Union, in any language listed in Annex IV, for the labelling, advertising material or commercial documents of a product which does not comply with this Regulation. Furthermore, no terms, including terms used in trademarks or company names, or practices shall be used in labelling or advertising if they are liable to mislead the consumer or user by suggesting that a product or its ingredients comply with this Regulation."

Descriptions of the organic product and translations of such descriptions are in principle possible. However, as regards the language of the labelling the following legislation shall be respected:

Article 15(1) of Regulation (EU) No 1169/2011 of the European Parliament and of the Council in respect of food labelling provides that: "*mandatory food information shall appear in a language easily understood by the consumers of the Member States where a food is marketed.*"

- Article 15(2) of Regulation (EU) No 1169/2011 provides that: "*Within their own territory, the Member States in which a food is marketed may stipulate that the particulars shall be given in one or more languages from among the official languages of the Union*"

- Article 15(3) of Regulation (EU) No 1169/2011 provides that: "*Paragraphs 1 and 2 shall not preclude the particulars from being indicated in several languages*".

6) In the EU do wholesalers dealing only with prepacked products need to be certified organic (bio certificate) in order to sell their products to retailers?

Yes. Regulation (EU) 2018/848 establishes the rules on organic production and labelling of organic products.

Operators selling organic products must adhere to the organic certification system in accordance with Article 34 of that regulation:

"Prior to placing any products on the market as organic or as in-conversion or prior to the conversion period, operators and group of operators referred to in Article 36 which produce, prepare, distribute, or store organic or in-conversion products, which import such products from a third country or export such products to a third country,

or which place such products on the market, shall notify their activity to the competent authorities of the Member State in which it is carried out and in which their undertaking is subject to the control system."

In addition, Article 34(2) of Regulation (EU) 2018/848 provides that "Operators that sell prepacked organic products directly to the final consumer or user shall be exempted from the notification obligation referred to in paragraph 1 of this Article and from the obligation to be in the possession of a certificate referred to in Article 35(2) provided they do not [...] store other than in connection with the point of sale [...]". In order for products to be sold 'directly to the final consumer at the point of sale' within the meaning of Article 35(2) of Regulation (EU) 2018/848, it is necessary for the sale to occur in the presence of both the operator or its sales personnel and the final consumer.

Therefore, distributors and wholesalers of organic products cannot be subject to the exemption from the organic control system.

7) When can retailers selling organic products be exempted by the notification and certification system?

Recital (84) of Regulation (EU) 2018/848, states that *"small retail shops not selling organic products other than prepacked organic products present a relatively low risk of non-compliance with organic production rules, and they should not face disproportionate burdens for selling organic products. They should therefore not be subject to the notification and certification obligations, but should remain subject to official controls performed for the verification of compliance with the rules governing organic production and the labelling of organic products [...]"*

Article 34(2) of Regulation (EU) 2018/848 provides that *"operators that sell prepacked organic products directly to the final consumer or user shall be exempted from the notification obligation referred to in paragraph 1 of this Article and from the obligation to be in the possession of a certificate referred to in Article 35(2) provided that they do not produce, prepare, store other than in connection with the point of sale, or import such products from a third country, or subcontract such activities to another operator"*.

The exemption can only be granted to operators that sell prepacked organic products directly to the final consumer or user, and provided they do not:

- produce, prepare,
- store other than in connection with the point of sale, or
- import such products from a third country, or
- subcontract such activities to another operator (= production, preparation including labelling, storage, import).

The concept of *"direct sale"* and *"storing in connection with the point of sale"* refers to a situation in which the sale of the prepacked organic products takes place where

the products are stored and when both the operator or its sales personnel and the final consumer are present at the same time.

A retailer selling pre-packed organic products but subcontracting the production, preparation (including labelling or alterations made to the labelling relating to organic production), storage or import activities to another operator cannot therefore benefit from the exemption set under Article 34(2) of Regulation (EU) 2018/848 and is subject to the organic certification and control system.

8) Can a group of operators certified as organic (Regulation (EU) No 2018/848) consist of members who are not organic farmers or organic operators that produce algae or aquaculture animals?

No. Group of operators can only be composed of members who are farmers or operators that produce algae or aquaculture animals and who in addition may be engaged in processing, preparation or placing on the market of food and feed. Moreover, farmers or operators that do not comply with Regulation (EU) No 2018/848 cannot be members of a group of operators certified as organic.

First, Article 36(1), point (a), defines the type of operators that can be members of a group of operators and the activities that members of a group of operators can perform: *"Each group of operators shall: (a) only be composed of members who are farmers or operators that produce algae or aquaculture animals and who in addition may be engaged in processing, preparation or placing on the market of food or feed;"*.

Second, the following provisions of Regulation (EU) No 2018/848 are also relevant:

- Article 3, point (13), which provides the following definition of "operator": *"Operator means the natural or legal person responsible for ensuring that this Regulation is complied with every stage of production, preparation and distribution that are under that person's control";* and
- Article 36(1), point (g), which provides as follows: *"Each group of operators shall [...] establish a system for internal controls comprising a documented set of control activities and procedures in accordance with which an identified person or body is responsible for verifying compliance with this Regulation of each member of the group."*

9) In an example of a cooperative that has more than 2000 members, can this cooperative have groups of operators as sub-units of the cooperative, which are certified as groups of operators but which remain under the cooperative or share the same legal personality as it?

No. On the one hand, in the context of this example, the sub-units mentioned are groups of operators for the purpose of organic certification in accordance with Article 36(1), point (d) of Regulation (EU) No 2018/848, which provides as follows: *"Each*

group of operators shall (...) have legal personality". Therefore, the mentioned sub-units cannot share the legal personality with other sub-units and/or cooperatives. On the other hand, Regulation (EU) No 2018/848 does not prevent a group of operators from participating in the membership of other types of farmers associations or arrangements such as a cooperative subject to the respect of all applicable provisions. Finally, as set out in Article 4 of Regulation (EU) No 2021/279, the size of a group of operators cannot exceed 2000 members.

10) When members of a certified group of operators no longer comply with the requirements set out in Article 36(1)(a) and (b) of Regulation (EU) No 2018/848 can they remain a member of the group of operators?

No. Article 36(1) of Regulation 2018/848 provides that each group of operators "*shall only be composed of members*" fulfilling, among other requirements, the conditions set out in points (a) and (b). Consequently, an operator who does not fulfil the requirements of Article 36(1), points (a) and/or (b) of Regulation 2018/848 cannot be a member of the group of operators if that group is intended to be controlled and certified as a group of operators within the meaning of Article 36 of Regulation (EU) No 2018/848.

11) Can the group of operators perform preparation activities on the products that it receives from its members?

Yes. A group of operators certified as organic in the EU, or a group of operators certified as organic in the third countries that has been subject to the controls referred to in Article 45(1)(b)(i) of Regulation (EU) No 2018/848 can perform any activity, including "preparation", under the group's certification. Those activities are: (i) the "production, preparation, distribution/placing on the market, storing, import and export" in the EU (Annex VI of Regulation (EU) No 2018/848); and (ii) "production, preparation, distribution, storing, import and export" in third countries (Annex I of Regulation (EU) No 2021/1378).

12) What are the requirements for an operator to become a member of a group of operators?

In order to become a member of a group of operators, an operator must comply with the requirements of Article 36 of Regulation (EU) No 2018/848. First, Article 36(1), point (a), defines the type of operators that can be members of a group of operators and the activities that members of a group of operators can perform: "*Each group of operators shall: (a) only be composed of members who are farmers or operators that produce algae or aquaculture animals and who in addition may be engaged in processing, preparation or placing on the market of food or feed*";

Second, Article 36(1), point (b), requires the members of a group of operators to meet one of three alternative criteria in terms of turnover or holding size in order to be eligible to be part of group of operators:

"only be composed of members (...) of which the individual certification cost represents more than 2 % of each member's turnover or standard output of organic production and whose annual turnover of organic production is not more than EUR 25 000";

"only be composed of members (...) whose standard output of organic production is not more than EUR 15 000 per year"; or

"only be composed of members (...) who have each holdings of maximum:

- five hectares,*
- 0.5 hectares, in the case of greenhouses, or*
- 15 hectares, exclusively in the case of permanent grassland".*

Third, Article 36(1), point (e), requires that a *"group of operators shall only be composed of members whose production activities or possible additional activities referred to in point (a) take place in geographical proximity to each other in the same Member State or in the same third country".*

13) What does it mean that group of operators "shall have legal personality" as required in Article 36(1)(d) of Regulation (EU) No 2018/848?

While Regulation (EU) No 2018/848 does not define the term "legal personality", that notion refers to those entities that are recognised by national law as having a distinct identity, as well as legal rights and duties, and are thus able to do things in law that a natural person can do (e.g. own property, enter into contracts etc) according to the laws of that country.

4. PRODUCTION RULES

4.1 GENERAL PRODUCTION RULES

1) What can happen in case of contamination of an organic farmland by chemicals used by neighbours operating as conventional farmers?

Regulation (EU) 2018/848 provides for specific production rules and labelling requirements that organic operators have to respect, as well as control requirements to be followed by the authorities performing controls and certification tasks. According to Article 28(1) of the above regulation, an organic operator has to draw up and subsequently maintain practical measures at the level of the unit and/or premises and/or activity to ensure compliance with the organic production rules as well as the precautionary measures to reduce the risk of contamination by unauthorised products or substances.

However, Regulation (EU) 2018/848 does not provide a procedure for resolving claims concerning unintentional contamination from a neighbouring holding. In these cases, a farmer can contact the competent authorities, control bodies or control authorities in its Member State as national laws may apply. When the operator is aware of a contamination, the product should not be marketed as organic.

2) How is the use and possible presence of genetically modified organisms (GMOs) avoided in organic production?

The use of GMOs in organic production is prohibited, except for veterinary medicinal products. Article 11 of Regulation (EU) 2018/848 establishes a prohibition on the use of any GMOs and products produced from, or by, GMOs as food, feed, processing aids, plant protection products, fertilisers, soil conditioners, plant reproductive material, micro-organisms and animals in organic production. The same Regulation defines “GMO” in its Article 3(58) as follows: “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 which is not obtained through the techniques of genetic modification listed in Annex I.B to that Directive;”.

In compliance with Article 11(2), for the purpose of the prohibition laid down in Article 11(1), with regard to GMOs and products produced from GMOs for food and feed, operators may rely on the labels accompanying a product or any other accompanying document, affixed or provided pursuant to Directive 2001/18/EC, Regulation (EC) 1829/2003 or Regulation (EC) 1830/2003. These labelling thresholds represent ceilings, which are exclusively linked to adventitious and technically unavoidable presence of GMOs.

As provided under Article 11(3), operators may assume that no GMOs or products produced from GMOs have been used in the manufacture of purchased food and feed products when the latter are not labelled, or accompanied by a document, pursuant to those Regulations, unless they have obtained other information indicating that labelling of the products in question is not in conformity with those regulations.

On the basis of the above mentioned legal provisions, no products containing GMOs can be used in organic production, except veterinary products and products whose labels do not indicate the presence of GMOs on the basis of Directive 2001/18/EC, Regulation (EC) 1829/2003 and Regulation (EC) 1830/2003, because the presence is due to adventitious and technically unavoidable presence that is below the labelling threshold of 0, 9%.

Finally, Article 11(4) provides that with regard to products not covered by above-mentioned labelling requirements, 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.

3) Can rodenticides be used in organic production?

Article 9(3) of Regulation (EU) 2018/848 provides that “for the purposes and uses referred to in Article 24 and 25 and in Annex II only products and substances that have been authorised pursuant to those provisions may be used in organic production provided that their use in non-organic production has also been authorised in accordance with the relevant provisions of Union Law and, where applicable, in accordance with national provisions based on Union law.”

The authorisation to use and market rodenticide as in plant protection products (PPPs) is the responsibility of each Member State, while the assessment and approval of the active substances, which are included in PPPs, are carried out at EU level. The list of approved active substances for use in PPPs is set out in Regulation (EC) No 1107/2009 and Regulation (EU) No 540/2011. From the active substances authorised at EU level, only those listed in Annex I of Commission Implementing Regulation (EU) 2021/1165 can be used in the composition of PPPs to be used in organic production.

Although no individual rodenticides are specifically mentioned in that list, the group of substances called "basic substances" can be used as rodenticides provided that such use is authorised at Member State level for general agriculture.

4) Can tap water be used in organic production?

The use of water in organic production is authorised in accordance with Part IV of Annex II point 2.2.2 of Regulation (EU) No 2018/848 (e) drinking water ...generally used in food processing.

In addition, in Section A2 (*processing aids and other products, which may be used for processing of ingredients of agricultural origin from organic production*) of Annex V to Commission Implementing Regulation (EU) 2021/1165, water is authorised in the processing of organic food with the specific condition that it is "*drinking water within the meaning Council Directive 98/83/EC*".

5) Can ionising radiation be used on organic production?

No. The use of ionising radiation for the treatment of organic food or feed, or of raw materials used in organic food or feed, is prohibited in accordance with Article 5 of Regulation (EU) No 2018/848. The ban covers the whole organic food chain.

Please note that Article 3(67) of Regulation (EU) 2018/848 provides that 'Ionising radiation' means ionising radiation as defined in point (46) of Council Directive 2013/59/Euratom.

4.2 PLANT PRODUCTION RULES

1) Which fertilisers can be used in organic farming?

Pursuant to Article 6 of Regulation (EU) No 2018/848, organic production shall be based among others on the maintenance and enhancement of soil life and natural soil fertility, soil stability, soil water retention and soil biodiversity, preventing and combating loss of soil organic matter, soil compaction and soil erosion, and the nourishing of plants primarily through the soil ecosystem. In addition, it shall be based also on the limitation of the use of non-renewable resources and external inputs to a minimum.

Point 1.9.2 of Part I of Annex II of Regulation (EU) No 2018/848 provides that "the fertility and biological activity of the soil shall be maintained and increased except in the case of grassland or perennial forage, by the use of by multiannual crop rotation including mandatory leguminous crops as the main or cover crop for rotating crops and other green manure crops".

Additionally, fertilisers and soil conditioners can be used only if they are authorised for use in organic production by the European Commission and included in a restricted list of products and substances (Annex 2 to Commission Implementing Regulation (EU) 2021/1165).

Mineral nitrogen fertilisers shall not be used according to point 1.9.8. of Part 1 of Regulation (EU) No 2018/848 and, in accordance with Article 24 of that regulation, fertilisers in organic farming can be authorised only if they comply with the objectives, criteria and principles of organic production, as established by the EU organic legislation. The Commission has the possibility to ask the group of experts for technical advice on organic production (EGTOP) for an opinion as to the compatibility of products or substances with the objectives, criteria and principles of organic production. This can be done after a relevant request is submitted to the Commission by a Member State.

2) Can pyrethrins containing pyperonylbutoxide (PBO) be used in organic farming?

PBO is a synergist and there is no EU list of synergists that can be added to plant protection products. The active substances used in plant protection products are authorised at EU level. Regulation (EU) No 540/2011 as amended by Commission Implementing Regulation (EU) No 798/2013 of 21 August 2013 approved pyrethrins as an active substance with a condition to limit its uses as an insecticide.

However, the authorisation of a plant protection product and its conditions of use (including its composition) is a responsibility of the Member States according to Regulation (EC) No 1107/2009. Thus, whether a plant protection product can contain PBO as a synergist is part of the authorisation given by that Member State. Therefore, whether the use of PBO is possible on the territory of a Member State will depend on the national authorisations allowing the use of plant protection products containing these substances.

With respect to organic, Annex I to Commission Implementing Regulation (EU) 2021/1165 establishes the list of active substances authorised in plant protection products to be used in organic farming. Pyrethrins extracted from plants such as *Chrysanthemum cinerariaefolium* are listed in Annex I. That means, that plant protection products containing pyrethrins *from plant origin* as an active substance can be used in organic farming as far as they are authorised by the competent authorities where the plant protection products containing them are marketed and used and according to the composition (including the use of synergists) approved by these authorities.

3) Which maximum residue limits (MRLs) apply to organic products?

Article 2(4) of Regulation (EU) No 2018/848 provides that, except where otherwise provided, the EU organic legislation applies without prejudice to related Union legislation, in particular legislation in the field of safety of the food chain, animal health and welfare, plant health and plant reproductive material. Therefore, all

organic products must respect general laws applied to conventional production, including Regulation (EC) No 396/2005 on MRLs of pesticides.

Furthermore, inputs for use in organic farming must be listed in Annex I (pesticides) and Annex II (fertilisers) to Commission Implementing Regulation (EU) 2021/1165. Substances listed in these annexes can only be used in so far as the corresponding use is authorised in conventional agriculture in the Member State concerned in accordance with the relevant EU legislation or national provisions in conformity with EU law as established in Article 9(3) of Regulation (EU) No 2018/848.

4) Which and how plant protection products (PPPs) are authorised in organic farming?

Pursuant to Article 24 of Regulation (EU) No 2018/848, substances can be authorised for use in organic production when they are listed in Annex I to Commission Implementing Regulation (EU) 2021/1165. However, Article 9(3) of Regulation (EU) No 2018/848 provides that “for the purposes and uses referred to in Article 24 and 25 and in Annex II only products and substances that have been authorised pursuant to those provisions may be used in organic production provided that their use in non organic production has also been authorised in accordance with the relevant provisions of Union Law and, where applicable, in accordance with national provisions based on Union law.” Thus, authorisation for the use of PPPs is granted nationally and the conditions for use and the composition of the PPP can differ among the Member States. Nevertheless, when it is used in one or more Member States, residues of the active substance are covered by the EU legislation on maximum residue levels (Regulation 396/2005) and Member States have to accept treated products if these residues are at or lower than the maximum residue level fixed.

In the EU, the authorisation to use and market a PPP is the responsibility of each Member State, while the assessment and approval of the active substances, which are included in PPPs, are carried out at EU level. The list of approved active substances for use in PPPs is set out Regulation (EC) No 1107/2009 and Regulation (EU) No 540/2011. From the active substances authorised at EU level, only those listed in Annex I of Commission Implementing Regulation (EU) 2021/1165 can be used in the composition of PPPs to be used in organic production.

5) Can chicory heads produced by hydroculture be sold as organic products?

In accordance with point 1.2 of Part I of Annex II of Regulation (EU) 2018/848, hydroponic production, which is a method of growing plants which do not naturally

grow in water with their roots in a nutrient solution only or in an inert medium to which a nutrient solution is added, is prohibited.

This prohibition results from the fact that hydroponic production, a method of growing plants with their roots in a nutrient solution only or in an inert medium to which a nutrient solution is added, is not in line with the overall principle of soil-related crop cultivation of organic production laid down in Article 5 of Regulation (EU) 2018/848. However, under point 1.3 of Part I of Annex II to that regulation, a derogation is granted to the production of chicory heads as follows: "By way of derogation from point 1.1, the following shall be allowed:(b) the obtaining of chicory heads, including by dipping them in clear water, provided that the plant reproductive material is organic. The use of a growing medium shall be allowed only when its components are authorised in compliance with Article 24."

6) Can a potential new technology for producing low cost nitrogen fertilisers be used in organic farming?

According to Annex II Part I point 1.9 of Regulation (EU) 2018/848, the fertility and biological activity of the soil shall be maintained and increased by multiannual crop rotation including legumes and other green manure crops, and by the application of livestock manure or organic material, both preferably composted, from organic production. In compliance with point 1.9.3 additionally fertilisers and soil conditioners can be used only if they are authorised for use in organic production by the Commission and included in a restricted list of products and substances (Annex II of Commission Implementing Regulation 2021/1165). Finally, under point 1.9.8 mineral nitrogen fertilisers are prohibited.

Pursuant to Article 24 of Regulation (EU) 2018/848, fertilisers in organic farming can be authorised provided they comply with the objectives, criteria and principles of organic production, as established by the EU organic legislation. The Commission has the possibility to ask the group of experts for technical advice on organic production (EGTOP) for an opinion as to the compatibility of products or substances with the objectives, criteria and principles of organic production. This can be done after a relevant request is submitted to the Commission by a Member State.

However, the EU organic legislation does not provide for the possibility to authorise or test new technologies for their production. Therefore, a possible authorisation would be on the final product and not on the specific technology, which has in any case to be in line with the EU organic legislation.

7) Can the product matrinal be used in organic production?

No. Pursuant to Article 24 of Regulation (EU) 2018/848, it is only possible to use active substances in plant protection products (PPPs), fertilisers, soil conditioners and nutrients which have been authorised and listed in Commission Implementing Regulation (EU) 2021/1165. Moreover, the use of matrinal or its similar compounds as plant protection product is not allowed in organic farming because these substances are not approved under Regulation (EC) 1107/2009 on placing of plant

protection products on the market and not included into Commission Implementing Regulation (EU) 2021/1165.

Before a fertiliser/soil conditioner/nutrient or plant protection product can be authorised for use in organic farming, it must be authorised and, based on the request of a Member State, it should be evaluated by EGTOP. After a positive advice by EGTOP, the substance can be included in the relevant annex of Commission Implementing Regulation (EU) 2021/1165.

8) Can ornamentals and herbs be produced "hors sol" and be certified organic ?

Yes, subject to the respect of certain conditions.

Point 1.4 of Part I of Annex II to Regulation (EU) 2018/848 provides that *"By way of derogation from point 1.1, the following practices shall be allowed: (a) growing plants for the production of ornamentals and herbs in pots to be sold together with the pot to the final consumer; (b) growing seedlings or transplants in containers for further transplanting"*.

Ornamentals and herbs can therefore be produced not only in living soils as laid down in point 1.1 of Part I of Annex II to Regulation (EU) 2018/848., but also in pots to be sold together with the pot to the final consumer.

The certification as organic is subject to the respect of all applicable rules. In particular, living soils and pots must be in line with the definition of *"soil-related crop cultivation"* of Article 3(70) of Regulation (EU) 2018/848: *"soil-related crop cultivation means production in living soil or in soil that is mixed or fertilised with materials and products that are allowed in organic production in connection with the subsoil and bedrock"*.

9) Is it possible to produce microgreens organically?

Yes. While "microgreens" is not a term used in Regulation (EU) 2018/848, given that microgreens are plants, they are subject to all the provisions concerning plants under that Regulation.

In accordance with point 1.1 of Part I of Annex II to Regulation (EU) 2018/848 *"Organic crops, except those which are naturally grown in water, shall be produced in living soil, or in living soil mixed or fertilised with materials and products allowed in organic production, in connection with the subsoil and bedrock."*

When microgreens are "sprouts", point 1.3 of Part I of Annex II to Regulation (EU) 2018/848 is relevant and provides as follows:

"

1.3. By way of derogation from point 1.1, the following shall be allowed:

(a) the production of sprouted seeds, which include sprouts, shoots and cress, solely living on the nutritional reserves available in the seeds, by moistening them in clear water, provided that the seeds are organic. The use of growing medium shall be prohibited, except the use of an inert medium intended solely to keep the seeds moist when the components of that inert medium are authorised in compliance with Article 24;

(b) the obtaining of chicory heads, including by dipping them in clear water, provided that the plant reproductive material is organic. The use of a growing medium shall be allowed only when its components are authorised in compliance with Article 24."

When microgreens are "herbs", point 1.4 of Part I of Annex II to Regulation (EU) 2018/848 is relevant and provides as follows:

"1.4. By way of derogation from point 1.1, the following practices shall be allowed:

(a) growing plants for the production of ornamentals and herbs in pots to be sold together with the pot to the final consumer;

(b) growing seedlings or transplants in containers for further transplanting."

10) Is vertical farming a system of production compatible with organic principles?

No, because the use of hydroponic production is prohibited by Regulation (EU) 2018/848 (point 1.2 of part I of Annex II to Regulation (EU) 2018/848): *"Hydroponic production, which is a method of growing plants which do not naturally grow in water with their roots in a nutrient solution only or in an inert medium to which a nutrient solution is added, is prohibited."*

This reflects one of the general principles of organic production as laid down in Article 5(f) of Regulation (EU) 2018/848 is the following: *"the appropriate design and management of biological processes, based on ecological systems and using natural resources which are internal to the management system, using methods that (...) practice soil-related crop cultivation and land-related livestock production (...)".*

Indeed, since the first EU Regulation on organic production (Regulation (EEC) 2092/91), organic plant production has been based on nourishing plants primarily through the soil ecosystem. Plants must be produced in living soil that is in connection with the subsoil and bedrock.

This is reflected in point 1.1. of part I of Annex II to Regulation (EU) 2018/848, which provides as follows: *"Organic crops, except those which are naturally grown in water, shall be produced in living soil, or in living soil mixed or fertilised with materials and products allowed in organic production, in connection with the subsoil and bedrock."*

However, part I of Annex II to Regulation (EU) 2018/848 contains certain limited exceptions to soil-related cultivation:

- point 1.3. for the production of sprouted seeds or chicory heads because this production requires particular techniques including in particular a period of time hors-soil;
- point 1.4. for the production of ornamentals and herbs that are sold in pots to the consumers for which the principle of soil-related crop cultivation is not adapted or for which no risk exists that the consumer could be misled regarding the production method;
- point 1.4. for growing seedlings or transplants in containers for further transplanting in order to facilitate availability of healthy young plant reproductive material; and
- point 1.5. for a transitional period up to 31 December 2031 for growing crops in demarcated beds in Finland, Sweden and Denmark but limited to the surfaces already certified before 28 June 2017.

These exceptions relate only to the requirement of cultivation in living soil in connection with the subsoil and bedrock, and all other organic production rules continue to apply, including the prohibition of hydroponic production.

11) May UV radiation be used in the organic production of mushrooms to increase the content of vitamin D?

No. Using UV radiation at the end of the production cycle to generate Vitamin D in mushrooms is not compatible with the objectives and principles of organic production laid down in Regulation (EU) 2018/848.

Pursuant to Article 5 of Regulation (EU) 2018/848, the EU legislation on organic production and labelling of organic products is based on respect for nature's system and cycles, the use of biological processes based on ecological systems and natural resources and the restriction of the use of external inputs: "Organic production (...) is based on the following general principles: (a) **respect for nature's systems and cycles** and the sustainment and enhancement of the state of the soil, the water and the air, of the health of plants and animals and of the balance between them; (...) (f) the appropriate design and management of **biological processes based on ecological systems and using natural resources** which are internal to the management system using methods that (i) use living organisms and mechanical production methods, (g) the **restriction of the use of external inputs**; where external inputs are required or the appropriate management practices and methods referred to in point (f) do not exist, the external inputs shall be limited to: (i) inputs from organic production; (ii) natural or naturally-derived substances; [...]"

12) Can "UV-light be applied during postharvest in organic horticultural products" in particular the application of " UV-B (280–315 nm) or UV-C (100–280 nm) irradiation in vegetables after harvest in order to prevent their decay caused by fungi" ?

No. Ionising radiation, which is defined in Article 3(67) of Regulation (EU) No 2018/848,¹⁴ is prohibited in the treatment of organic food and feed or other raw materials used in organic food or feed under Article 5 of Regulation (EU) No 2018/848. The prohibition covers the whole organic food chain.

Moreover, Article 5 of that regulation establishes that organic farming must be based on the following specific principles: "(c) *the responsible use of energy*" and "(g) *the restriction of the use of external inputs...*".

13) Can parallel production of organic and non-organic mushrooms take place in the same production unit?

No. Mushroom species are perennial. A holding must therefore be split into clear and effective separate production units for organic, in-conversion and non-organic production in line with the following provisions of Regulation (EU) 2018/848.

First, Article 9(2) of Regulation (EU) 2018/848 provides the following: "*The entire holding shall be managed in compliance with the requirements of this Regulation that apply to organic production.*"

Second, Articles 9(7) and 9(8) further provide the following:

"(7) *Notwithstanding paragraph 2, a holding may be split into clearly and effectively separated production units for organic, in-conversion and non-organic production, provided that for the non-organic production units: (a) as regards livestock, different species are involved; (b) as regards plants, different varieties that can be easily differentiated are involved. As regards algae and aquaculture animals, the same species may be involved, provided that there is a clear and effective separation between the production sites or units.*"

"(8) *By way of derogation from point (b) of paragraph 7, **in the case of perennial crops which require a cultivation period of at least three years, different varieties that cannot be easily differentiated, or the same varieties, may be involved, provided that the production in question is within the context of a conversion plan, and provided that the conversion of the last part of the area related to the production in question to organic production begins as soon as possible and is completed within a maximum of five years.** In such*

¹⁴ "Ionising radiation" means ionising radiation as defined in point (46) of Article 4 of Council Directive 2013/59/Euratom".

cases: (a) the farmer shall notify the competent authority, or, where appropriate, the control authority or the control body, of the start of harvest of each of the products concerned at least 48 hours in advance; (b) upon completion of the harvest, the farmer shall inform the competent authority, or, where appropriate, the control authority or the control body, of the exact quantities harvested from the units concerned and of the measures taken to separate the products; (c) the conversion plan and the measures to be taken to ensure the effective and clear separation shall be confirmed each year by the competent authority, or, where appropriate, by the control authority or the control body, after the start of the conversion plan."

14) Is it possible to produce organic plants or plants products in boxes?

No, because plants produced in boxes are not produced in living soil that is in connection with the subsoil and bedrock, and there is no exception for production in boxes in Regulation (EU) 2018/848.

Article 5(f) of Regulation (EU) 2018/848 is relevant and provides as follows: *"the appropriate design and management of biological processes, based on ecological systems and using natural resources which are internal to the management system, using methods that (...) practice soil-related crop cultivation and land-related livestock production (...)"*.

Indeed, since the first EU Regulation on organic production (Regulation (EEC) 2092/91), organic plant production has been based on nourishing plants primarily through the soil ecosystem. Plants must be produced on and in living soil in connection with the subsoil and bedrock.

This is reflected in point 1.1. of part I of Annex II to Regulation (EU) 2018/848, which provides as follows: Point 1.1. of part I of Annex II to Regulation (EU) 2018/848 adds: *"Organic crops, except those which are naturally grown in water, shall be produced in living soil, or in living soil mixed or fertilised with materials and products allowed in organic production, in connection with the subsoil and bedrock."*

However, part I of Annex II to Regulation (EU) 2018/848 contains certain limited exceptions to soil-related cultivation:

- point 1.3. for the production of sprouted seeds or chicory heads because these productions requires particular techniques including in particular a period of time hors-soil;
- point 1.4. for the production of ornamentals and herbs that are sold in pots to the consumers for which the principle of soil-related crop cultivation is not adapted or for which no risk exists that the consumer could be misled regarding the production method;

- point 1.4. for growing seedlings or transplants in containers for further transplanting in order to facilitate availability of healthy young plant reproductive material; and
- point 1.5. for a transitional period up to 31 December 2031 for growing crops in demarcated beds in Finland, Sweden and Denmark but limited to the surfaces already certified before 28 June 2017.

These exceptions relate only to the requirement of cultivation in living soil in connection with the subsoil and bedrock, and all other organic production rules continue to apply, including the prohibition of hydroponic production.

15) Is it possible to produce organic plants or plants products in hydroponia ?

No. Point 1.2. of Part I of Annex II to Regulation (EU) 2018/848 prohibits such a method of production: *"Hydroponic production, which is a method of growing plants which do not naturally grow in water with their roots in a nutrient solution only or in an inert medium to which a nutrient solution is added, is prohibited. "*

16) Is it possible to use conventional straw in organic production?

Yes, but subject to strict conditions.

First, Article 5 of Regulation (EU) 2018/848 laying down the general principles for the organic production provides as follows: *"Organic production is a sustainable management system that is based on the following general principles:*

*(f) the appropriate design and management of biological processes based on ecological systems and **using natural resources which are internal to the system by methods that:***

(i) use living organisms and mechanical production methods;

*(ii) **practice soil-related crop cultivation and land-related livestock production** or practice aquaculture which complies with the principle of sustainable exploitation of aquatic resources;*

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

*(iv) are based on risk assessment, and **the use of precautionary measures and preventive measures**, where appropriate;*

*(g) **the restriction of the use of external inputs.** Where external inputs are required or the appropriate management practices and methods referred to in point (f) do not exist, the external input shall be limited to:*

*(i) **inputs from organic production, in the case of plant reproductive material priority shall be given to varieties selected for their ability to meet the specific needs and objectives of organic agriculture;***

*(ii) **natural or naturally-derived substances;***

(iii) low solubility mineral fertilisers;”.

Second, Article 6 of Regulation (EU) 2018/848 requires that organic production be based, among others, on the principle that *“(b) the limitation of the use of non-renewable resources and external inputs to a minimum”.*

Third, point 1.9.2 of part I of Annex II to Regulation (EU) 2018/848 provides as follows: *“the fertility and biological activity of the soil shall be maintained and increased (a) except in the case of grassland or perennial forage, by the use of multiannual crop rotation including mandatory legumes crops as the main or cover crop for rotating crops and other green manure crops; (b) in the case of greenhouses or perennial crops other than forage by the use of short-term green manure crops and legumes as well as the use plant diversity; and (c) in all cases, by the application of livestock manure or organic matter, both preferably composted, from organic production.”.*

Fourth, point 1.9.1.2(b) of part II of the same Annex requires specific housing and husbandry practices for animals that *“housing shall be provided with a comfortable, clean and dry laying or rest area of sufficient size, which shall consist of a solid construction which is not slatted. Ample dry bedding strewn with litter material shall be provided in the rest area. The litter shall **comprise straw or other suitable natural material. The litter may be improved and enriched with any mineral product that is authorised pursuant to Article 24 as a fertiliser or soil conditioner for use in organic production.**”*

Fifth, Article 28 of Regulation (EU) 2018/848 requires operators to draw up and subsequently maintain precautionary measures to avoid the presence of non-authorised products and substances.

Based on the above, it is therefore possible to use conventional straw for bedding in organic livestock production. However, operators must give priority to the use of organic or in-conversion straw.

Moreover, given that, due to unexpected conditions such as adverse climatic events, the availability of organic and in-conversion straw might be limited, operators may have to rely on non-organic off-farm inputs although this should not be the common practice.

Operators must also ensure that any critical processing step does not jeopardise the integrity of organic products. This is particularly relevant when off-farm inputs are used such as straw, given the risks of contamination because conventional straw may contain, among others, residues of pesticides.

Finally, precautionary measures to avoid the presence of non-authorised products and substances could include analyses of external inputs. It is the responsibility of operators to identify and apply the appropriate precautionary measures to ensure the integrity of the specific organic production.

17) Is it possible to use railway sleepers for the support of fences in an organic farm?

Yes.

Article 28 of Regulation (EU) 2018/848 requires organic operators to draw up and maintain all the practical measures to ensure compliance with the organic production rules and to take precautionary measures to reduce the risk of contamination of their organic production by unauthorised products or substances.

Given that railway sleepers are often treated with toxic chemical substances such as creosote, the risk of contamination must therefore be taken into account if they are used in organic production.

18) Can extracts of stevia leaves be certified under organic legislation?

No.

Extracts of *Stevia rebaudiana* Bertoni are steviol glycosides, extracted from leaves of *Stevia rebaudiana* Bertoni, authorised in the EU as E960 under Regulation (EC) 1333/2008 on food additives.

Moreover, Article 7 of Regulation (EU) 2018/848 provides as follows: "*The production of processed organic food shall be based, in particular, on the following specific principles: (a) the production of organic food from organic agricultural ingredients; (b) the restriction of the use of food additives, of non-organic ingredients with mainly technological and sensory functions, and of micronutrients and processing aids, so that they are used to a minimum extent and only in cases of essential technological need or for particular nutritional purposes; c) the exclusion of substances and processing methods that might be misleading as regards the true nature of the product. d) the processing of organic food with care, preferably through the use of biological, mechanical and physical methods.*"

Steviol glycosides are not therefore allowed for use in organic production.

19) Can non-organic clove oil be used as a plant protection product on organic limes?

Yes.

Article 24 of Regulation (EU) 2018/848 provides that: "*The Commission may authorise certain products and substances for use in organic production, and shall include any such authorised products and substances in restrictive lists, for the*

following purposes: (a) as active substances to be used in plant protection products; (...)".

Article 9 of Regulation (EU) 2018/848 further provides that: *"For the purposes and uses referred to in Articles 24 and 25 and in Annex II, only products and substances that have been authorised pursuant to those provisions may be used in organic production, provided that their use in non-organic production has also been authorised in accordance with the relevant provisions of Union law and, where applicable, in accordance with national provisions based on Union law."*

According to the above-referred provisions, only active substances that are to be used in the plant protection products authorised and listed in Annex I to Regulation (EU) 2021/1165 may therefore be used in organic production. One of the products that is authorised in organic production and listed in that Annex is "clove oil". The use of clove oil is authorised in organic production, except for use as herbicide. Clove oil is not required to be certified organic or obtained from organic raw material.

20) Are herbicides allowed to be used in organic production

No.

Herbicides have not been included in the list of approved active substances to be used in organic production, as laid down in Commission Implementing Regulation (EU) 2021/1165.

As provided for in Point 1.10.1 of Part I of Annex II to Regulation (EU) 2018/848: *"The prevention of damage caused by pests and weeds shall rely primarily on the protection by:*

- natural enemies,*
- the choice of species, varieties and heterogeneous material,*
- crop rotation,*
- cultivation techniques such as biofumigation, mechanical and physical methods, and*
- thermal processes such as solarisation and, in the case of protected crops, shallow steam treatment of the soil (to a maximum depth of 10 cm)."*

Primarily agronomic practices and biological and physical methods must therefore be applied in organic production for the control of weeds.

However, point 1.10.2 of Part I of Annex II provides for the following exceptions if there are pests or an established threat to a crop: *"1.10.2. Where plants cannot adequately be protected from pests by measures provided for in point 1.10.1 or in the case of an established threat to a crop, only products and substances authorised pursuant to Articles 9 and 24 for use in organic production shall be used, and only to the extent necessary. Operators shall keep records proving the need for the use of*

such products, including the date or dates on which each product was used, the name of the product, its active substances, the amount applied, the crop and parcels concerned, and the pest or disease to be controlled."

The definition of "pest", which is laid down under Article 3, point (24), of Regulation (EU) 2018/848, is as follows: "(24) 'pest' means a pest as defined in Article 1(1) of Regulation (EU) 2016/2031 of the European Parliament and of the Council"

Article 1(1) of Regulation (EU) 2016/2031 provides that: "1. This Regulation establishes rules to determine the phytosanitary risks posed by any species, strain or biotype of pathogenic agents, animals, or parasitic plants injurious to plants or plant products ('pests') and measures to reduce those risks to an acceptable level."

Points 1 and 4 of Annex I to Commission Implementing Regulation (EU) 2021/1165 approved the use of several basic and active substances except as herbicides.

Parasitic plants are therefore included in the definition of pest. Active substances to be used as herbicides in organic production if the circumstances of point 1.10.2 are met, could potentially be assessed, and approved under Article 24 of Regulation (EU) 2018/848. At present, no active substance has been authorised for use as herbicide in organic production and the current provisions prohibit the use of authorised basic substances as herbicides.

21) Can electric weeding be applied on organic crops?

Yes, but under strict conditions.

There are no specific provisions concerning electric weeding techniques in the EU legislation on organic production. However, it can be deduced from point 1.10.1 of Part I of Annex II to Regulation (EU) 2018/848 that these techniques, which are "physical methods", could be permitted: *"The prevention of damage caused by pests and weeds shall rely primarily on the protection by: — natural enemies, — the choice of species, varieties and heterogeneous material, — crop rotation, — cultivation techniques such as biofumigation, mechanical and physical methods, and — thermal processes such as solarisation and, in the case of protected crops, shallow steam treatment of the soil (to a maximum depth of 10 cm)".*

Such physical methods must respect all the applicable provisions on organic production and, in particular, be applied in compliance with the general principles of organic production. Articles 5(a) and (c), of Regulation (EU) 2018/848 are relevant and provides as follows: *"respect for nature's systems and cycles and the sustainment and enhancement of the state of the soil, the water and the air, of the health of plants and animals, and of the balance between them; " and " the responsible use of energy and natural resources, such as water, soil, organic matter and air".*

4.2.1. PLANT REPRODUCTIVE MATERIAL

Introduction

Plants can reproduce themselves via seeds (sexual reproduction, except cases of apomixis) or via vegetative propagation (asexual reproduction). Depending on the characteristics of the plant species and the breeding objectives, there are several possible techniques to reproduce a plant through seeds, tubers, bulbs, seedlings, cuttings, layerings, grafting via buds, scions, rootstock etc.

Article 3, point (17), of Regulation (EU) 2018/848 provides the following definition of plant reproductive material (PRM): *“plant reproductive material” means plants and all parts of plants, including seeds, at any stage of growth that are capable of, and intended for, producing entire plants*”.

Moreover, Article 3, point (20) of Regulation (EU) 2018/848 provides the following definition of mother plant: *“mother plant” means an identified plant from which plant reproductive material is taken for the reproduction of new plants*”.

In practice, all types of PRM initially have a “mother plant” within the meaning of Article 3, points (17) and (20), of Regulation (EU) 2018/848 because the function of PRM is the reproduction of plants.

To give five examples: (i) in the case of cereals, seeds to be used as PRM are harvested from “mother plants” that have been grown to produce seeds as PRM to reproduce the final plants; (ii) tomato seedlings are PRM derived from tomato seeds taken from a tomato mother plant to reproduce the plants; (iii) stolons are PRM taken from a strawberry mother plant to reproduce the plants; (iv) scions are cuttings taken from a mother plant to be grafted on a rootstock to reproduce the plants; and (v) rootstock are derived from a mother plant to reproduce the plant.

Organic varieties or organic heterogeneous materials used in the production of PRM suitable for organic farming can be bred and marketed in line with the provisions of Regulation (EU) 2018/848, of Commission Delegated Regulation (EU) 2021/1189 and of the relevant horizontal rules¹⁵.

The Commission services are currently considering new provisions concerning a temporary experiment on organic varieties to take into account the high level of genetic and phenotypical diversity in these organic varieties, and to set principles for their examination which are adapted to the organic sector.

¹⁵ [Plant reproductive material \(europa.eu\)](https://european-council.europa.eu/media/e300042f-323d-4761-995d-6f9369b3114c/default.aspx?docId=32382&lang=en)

1) Can organic heterogeneous material be sold to any operator not certified organic?

Yes. Articles 13(1) and (2) of Regulation (EU) 2018/848 provide for specific derogations from the relevant horizontal rules¹⁶. Those derogations govern the marketing of PRM of organic heterogeneous material to facilitate its availability. Those horizontal rules concern various species of fodder plant seeds, cereal seeds, vine, ornamentals, agricultural plant species, vegetables and fruit, beet, seed potatoes, oil and fibre plants.

On the basis of Articles 13(3) and 38(8), point (a)(ii), of Regulation (EU) 2018/848 the Commission has adopted Delegated Regulation (EU) 2021/1189 supplementing that regulation by setting out rules governing the production and marketing of PRM of organic heterogeneous material.

Those provisions do not restrict the sale of organic heterogeneous material only to organic operators.

2) Are seedlings plant reproductive material?

Yes. "Seedlings" are young plants originating from seeds and not from cuttings. They fall under the definition of PRM in Article 3, point (17), of Regulation (EU) 2018/848.

3) May "seedlings of Christmas trees" certified organic in one Member State be marketed as organic in another Member State?

Yes. Seedlings of Christmas trees are PRM within the meaning of Article 3, point (17), of Regulation (EU) 2018/848 when they are used to produce small Christmas trees. This is because Article 3(17) defines PRM *plants and all parts of plants, including seeds, at any stage of growth that are capable of, and intended for, producing entire plants*" (emphasis added).

¹⁶ (i) Council Directive 66/401/EEC of 14 June 1966 on the marketing of fodder plant seed (OJ L 125, 11.7.1966, p.2298); (ii) Council Directive 66/402/EEC of 14 June 1966 on the marketing of cereal seed (OJ L 125, 11.7.1966, p.2309); Council Directive 68/193/EEC of 9 April 1968 on the marketing of material for the vegetative propagation of the vine (OJ L 93, 17.4.1968, p.15); (iii) Council Directive 98/56/EC of 20 July 1998 on the marketing of propagating material of ornamental plants (OJ L 226, 13.8.1998, p.16); (iv) Council Directive 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species (OJ L 193, 20.7.2002, p.1); (v) Council Directive 2002/54/EC of 13 June 2002 on the marketing of beet seed (OJ L 193, 20.7.2002, p.12); (vi) Council Directive 2002/55/EC of 13 June 2002 on the marketing of vegetable seed (OJ L 193, 20.7.2002, p.33); (vii) Council Directive 2002/56/EC of 13 June 2002 on the marketing of seed potatoes (OJ L 193, 20.7.2002, p.60); (viii) Council Directive 2002/57/EC of 13 June 2002 on the marketing of seed of oil and fibre plants (OJ L 193, 20.7.2002, p.74); (ix) Council Directive 2008/72/EC of 15 July 2008 on the marketing of vegetable propagating and planting material, other than seed (OJ L 205, 1.8.2008, p.28); and (x) Council Directive 2008/90/EC of 29 September 2008 on the marketing of fruit plant propagating material and fruit plants intended for fruit production (OJ L 267, 8.10.2008, p.8).

As a result, seedlings of Christmas trees that are certified as organic in one Member State must be recognised and accepted for production of organic Christmas trees in all other Member States.

4) Can organic farmers use their self-produced seeds?

Yes. Organic farmers, like all farmers, can use self-produced seeds as long as they respect the relevant horizontal rules on variety rights set out in Regulation (EC) 2100/94 on Community plant variety rights. On the one hand, Article 13 of that regulation provides that the holder of varieties subject to the Community plant varieties rights can authorise under certain conditions the production, reproduction or marketing of such varieties. On the other hand, Article 14 of that regulation provides that, for certain agricultural plant species, farmers are allowed to freely use the product of the harvest which they have obtained on their own holding, by planting propagating material of a variety other than a hybrid or synthetic variety, which is covered by a Community plant variety right under certain conditions for propagating purposes in the field (on their own holding). Finally, Article 15 of Regulation (EC) 2100/94 provides for certain limitations of the effects of Community plant variety rights. These include "*the acts done for the purpose of breeding, or discovering and developing other varieties*" that are considered as a "breeder's exemption".

For more information: https://food.ec.europa.eu/plants/plant-variety-property-rights_en.

5) When can plant reproductive material be labelled as "organic" and bear the EU organic logo?

PRM can be labelled as organic and bear the EU organic logo when the PRM meets the requirements of point 1.8.2. of Part I of Annex II to Regulation (EU) 2018/848, which provides that: *"To obtain **organic plant reproductive material** to be used for the production of products other than plant reproductive material, **the mother plant and, where relevant, other plants intended for plant reproductive material production shall have been produced in accordance with this Regulation for at least one generation, or, in the case of perennial crops, for at least one generation during two growing seasons.**"*

PRM can also be labelled as organic and bear the EU organic logo when the competent authorities permit the production of PRM under the conditions in point 1.8.6 of Part I of Annex II to Regulation (EU) 2018/848 i.e. *"when mother plants or, where relevant, other plants intended for the production of plant reproductive material and produced in compliance with point 1.8.2 are not available in sufficient quantity or quality"*.

6) When can plant reproductive material be labelled as "in-conversion"?

Pursuant to Articles 10(4) and 30(3) of Regulation (EU) 2018/848, PRM can be labelled as in-conversion once the land parcel on which the PRM is grown has completed a 12 month in-conversion period.

Article 10(4) of Regulation (EU) 2018/848 provides as follows: *"...the following products produced during the conversion period and in compliance with paragraph 1 may be marketed as in-conversion products: (a) plant reproductive material, provided that a conversion period of at least 12 months has been complied with;....*

Article 30(3) provides as follows: *"Products that have been produced during the conversion period shall not be labelled or advertised as organic products or as in-conversion products. However, plant reproductive material, food products of plant origin and feed products of plant origin **that have been produced during the conversion period, which comply with Article 10(4),** may be labelled and advertised as in-conversion products by using the term 'in-conversion' or a corresponding term, together with the terms referred to in paragraph 1."*

7) Can in-conversion plant reproductive material bear the EU organic logo?

No. For in-conversion products (and then for in-conversion PRM), the EU organic logo cannot be used as this is prohibited by the last paragraph of Article 33(1) of

Regulation (EU) 2018/848: *"The organic production logo of the European Union shall not be used for processed food as referred to in points (b) and (c) of Article 30(5) and for in-conversion products as referred to in Article 30(3)."*

8) May an organic nursery operator be granted an authorisation to produce organic plant reproductive material in cases where there is a lack of mother plants produced in accordance with point 1.8.2. of Part I of Annex II to Regulation (EU) 2018/848?

Yes. Organic PRM must be used by the organic producers as laid down in point 1.8.1 of Part I of Annex II to Regulation (EU) 2018/848: *"for the production of plants and plant products. other than plant reproductive material, only organic plant reproductive material shall be used".*

For the producers of PRM, point 1.8.2. of Annex II Part I provides as follows: *"To obtain **organic plant reproductive material** to be used for the production of products other than plant reproductive material, **the mother plant and, where relevant, other plants intended for plant reproductive material production shall have been produced in accordance with this Regulation for at least one generation, or, in the case of perennial crops, for at least one generation during two growing seasons.**"*

Given the low availability of organic and in-conversion PRM in several crops and varieties, a system of derogations is set out in point 1.8.5 of Part I of Annex II to Regulation (EU) 2018/848 in order to allow farmers to use non-organic PRM for the various organic productions, **other than PRM**, when organic and in-conversion PRM is not available.

The competent authorities may authorise nursery operators to produce PRM for organic production subject to the conditions set out in point 1.8.6 of Part I of Annex II to Regulation (EU) 2018/848. PRM authorised according to point 1.8.6 will be produced in accordance with organic requirements and can therefore be labelled as organic with the possible use of the EU organic logo.

9) What should be understood as a "mother plant" under point 1.8.2 of Part I of Annex II to Regulation (EU) 2018/848 and what is the relationship of this provision with the horizontal rules that also refer to mother plants under the certification system of fruit propagation material?

"Mother plant" under point 1.8.2 of Part I of Annex II to Regulation (EU) 2018/848 should be understood in the same way as under Article 3(20) of Regulation (EU) 2018/848, which defines "mother plant" by reference to the origin of the final organic PRM that is placed on the market as an organic product.

For example, in case of grafted fruit plants to be transplanted and used for organic production (such as apples), the “mother plant” is the plant origin of the graft as well as the plant origin of the rootstock from which the fruit plants marketed as organic are produced.

As for the relationship between point 1.8.2 of Part I of Annex II to Regulation (EU) 2018/848 and the horizontal rules that also refer to mother plants, those latter rules establish specific requirements for the certification of PRM (identity, health and quality) for grouped species (e.g. cereal seeds, fruit plant propagating material, etc)¹⁷.

10) How should the provisions of point 1.8.2 of Part I of Annex II to Regulation (EU) 2018/848 related to the origin of organic plants apply?

The provisions of point 1.8.2 of Part I of Annex II to Regulation (EU) 2018/848 related to the origin of organic plants provide that minimum growing periods should apply when growing the mother plant or other plants that are at the origin of the final organic plant reproductive material.

Point 1.8.2 of Part I of Annex II to Regulation (EU) 2018/848 provides as follows: *“To obtain **organic plant reproductive material** to be used for the production of products other than plant reproductive material, **the mother plant and, where relevant, other plants intended for plant reproductive material production shall have been produced in accordance with this Regulation for at least one generation, or, in the case of perennial crops, for at least one generation during two growing seasons.**”*

Part I of Annex I to Regulation (EU) 2018/848 lays down plant production rules and in particular under its point 1.8. “Origin of plants including plant reproductive material”, lays down detailed provisions concerning the origin of PRM used for the production of organic products.

While the PRM (e.g. apple fruit tree) used for the production of organic products (e.g. organic apples) must be organic in compliance with point 1.8.1 of Regulation (EU)

¹⁷ Mother plant is defined only in Article 1 of Commission Implementing Directive 2014/98/EU implementing Council Directive 2008/90/EC as regards specific requirements for fruit plants: “(1) ‘mother plant’ means an identified plant intended for propagation; (2) ‘proposed pre-basic mother plant’ means a mother plant which the supplier intends to have accepted as a pre-basic mother plant; (3) ‘pre-basic mother plant’ means a mother plant intended for the production of pre-basic material; (4) ‘basic mother plant’ means a mother plant intended for the production of basic material; (5) ‘certified mother plant’ means a mother plant intended for the production of certified material”.

2018/848¹⁸, in cases of production of organic PRM, the PRM (mother plant/other plant) used to produce the organic PRM must comply with point 1.8.2 of Regulation (EU) 2018/848. These are therefore specific requirements for conventional origin material to be produced under organic conditions.

Article 3, point (20), of Regulation (EU) 2018/848 provides for a definition of mother plant as follows: *"mother plant means an identified plant from which plant reproductive material is taken for the reproduction of new plants"*.

Article 3, point (21), of Regulation (EU) 2018/848 establishes the following definition of "generation": *"'generation' means a group of plants constituting a single step in the line of descent of plants"*.

Point 1.8.2 of Part I of Annex II to Regulation (EU) 2018/848 requires that the production of the final organic PRM should originate from plants grown under organic production conditions (e.g. restricted use of fertilisers and pesticides) for at least a certain period of time.

Thus: (i) in the case of perennial species¹⁹ (e.g. apple, vines, etc.), organic PRM should originate from "mother plants" (regardless of their origin and of whether or not organic) grown for at least two growing seasons under organic conditions; and (ii) in the case of non-perennial species such as annual/biannual plants/crops (e.g. wheat, tomatoes, cauliflower, etc...), organic PRM should originate from "mother plants" grown for at least one generation. Article 3, point (21), of Regulation (EU) 2018/848 defines "generation" as *"a group of plants constituting a single step in the line of descent of plants"* (see further below answer to question 12).

Moreover, in cases of grafting, the PRM taken from the "mother plant" does not lead directly to a final new plant but may need some intermediate stages. In particular, in the case of the grafting of fruit or grapevines as well as of vegetables (e.g. Solanaceae), scion and rootstock originate from different mother plants (in some cases even from different species) and are grown and grafted under organic conditions to develop the final new plant.

This is the reason why point 1.8.2. refers to *"where relevant" other plants intended for the production of plant reproductive material,*". Indeed in the cases of grafting, other plants are rootstocks and scions that could also be propagated and grown under organic conditions for at least two growing seasons (in case of perennials) or at least one generation (in case of non-perennials) and lead to a final planting material labelled as organic.

¹⁸ "For the production of plants and plant products other than plant reproductive material, only organic plant reproductive material shall be used."

¹⁹ Article 9(8) of Regulation (EU) 2018/848 refers to perennial crops as requiring "a cultivation period of at least three years".

11) How should “two growing seasons” in point 1.8.2 of Part I of Annex II to Regulation (EU) 2018/848 be understood?

The term “two growing seasons” in point 1.8.2 of Part I of Annex II to Regulation (EU) 2018/848 refers to a period of almost two years, depending on the climate and time of sowing of the plant species. This is because the growing season is the period of the year when plants grow, and depends on climatic conditions. In Europe, for most species, the growing season can be considered as the period from spring to autumn.

12) How should “one generation” be understood in point 1.8.2 of part I of Annex II to Regulation (EU) 2018/848?

Article 3, point (21), of Regulation (EU) 2018/848 defines “generation” as follows: *“‘generation’ means a group of plants constituting a single step in the line of descent of plants”*.

Under point 1.8.2 of Part I of Annex II to Regulation (EU) 2018/848, “one generation” therefore refers to a cycle of reproduction of mother plants/other plants that should occur under organic conditions, i.e. from initial PRM to final plant.

Moreover, in the case of perennials, given that a “mother plant” can live several years, “one generation” refers to at least two growing seasons. After at least two such seasons, the type of reproductive material needed (seeds, scions, cuttings, etc...) can be harvested from the mother or other plants, as organic propagating plant material to propagate the crop.

13) Given the prohibition to authorise the use of non-organic seedlings under point 1.8.5.8 of Part I of Annex II to Regulation (EU) 2018/848 for “species that have a cultivation cycle completed in one growing season, from the transplantation of the seedling to the first harvest of product”, how can farmers grow these species in cases of a lack of availability of organic or in-conversion seeds and seedlings for such species?

Farmers must be authorised to use conventional seeds for growing species that have a cultivation cycle completed in one growing season, from the transplantation of the seedling to the first harvest of product.

Farmers can request the authorisation to use conventional seeds under point 1.8.5.1 of Part I of Annex II to Regulation (EU) 2018/848 and produce their own seedlings organically.

In addition, nurseries/PRM operators can place organic seedlings on the market when authorised by the competent authorities of the Member States under point 1.8.6 of Part I of Annex II to Regulation (EU) 2018/848. With such authorisation, nurseries/PRM, operators can produce organic seedlings in compliance with the conditions of point 1.8.6, when facing a lack of organically grown mother plants to originate seeds for organic seedlings.

14) *Is it possible to have the same type of PRM that is authorised under 1.8.6 of Part I of Annex II to Regulation (EU) 2018/848 placed on the market if this PRM is in-conversion?*

Yes. The decision on whether to authorise the production of PRM under point 1.8.6 of Part I of Annex II to Regulation (EU) 2018/848 shall be taken by the competent authorities of the Member States.

Given the availability on the market of PRM in-conversion may be insufficient to cover the demand, the competent authorities may authorise operators to produce PRM under the conditions set out in point 1.8.6 of Part I of Annex II to Regulation (EU) 2018/848.

15) *Which type of PRM can be authorised for use to produce organic PRM in accordance with point 1.8.6. of Part I of Annex II to Regulation (EU) 2018/848?*

All types of PRM - except seedlings from species that have a cultivation cycle completed in one growing season from the transplantation of the seedling to the first harvest of product (see point 1.8.6(b) of Part I of Annex II to Regulation (EU) 2018/848) - can be authorised to produce organic PRM in accordance with point 1.8.6 of Part I of Annex II to Regulation (EU) 2018/848.

16) *How should the derogation for plants grown in pots and containers as set out in point 1.4 of Part I of Annex II to Regulation (EU) 2018/848 be applied?*

Point 1.4 of Part I of Annex II concerns certain plants to be grown in pots and containers and is a derogation to the soil-related crop requirement laid down in point 1.1 of Part I of Annex II to Regulation (EU) 2018/848. Consequently, all other relevant organic production rules also apply to plants grown in pots and containers.

The above-mentioned derogation concerns two different categories of products: (i) ornamentals plants and herbs that are sold to final consumers in a pot; and (ii) seedlings and transplants in containers for further transplanting.

The first category - ornamentals plants and herbs that are sold to final consumers in pots - must be produced in compliance with point 1.8.1 of Part I of Annex II to Regulation (EU) 2018/848 for organic PRM or with point 1.8.5 of Part I of Annex II to Regulation (EU) 2018/848 for in-conversion or non-organic PRM where there is a lack of organic PRM.

The second category - seedlings or transplants grown in containers for further transplanting - must be produced in compliance with the provisions of point 1.8.2 of Part I of Annex II to Regulation (EU) 2018/848 on PRM, which provides that: *“To obtain organic plant reproductive material to be used for the production of products other than plant reproductive material, the mother plant and, where relevant, other plants intended for plant reproductive material production shall have been produced in accordance with this Regulation for at least one generation, or, in the case of perennial crops, for at least one generation during two growing seasons”*.

In addition, in accordance with point 1.8.6 of Part I of Annex II to Regulation (EU) 2018/848, when operators producing PRM do not have mother plants available that are grown in compliance with the requirements of point 1.8.2, they can be authorised to produce PRM originated from conventional PRM but grown organically in line with point 1.8.6 conditions, and they can be authorised to label this PRM as organic.

17) When can herbs and ornamentals plants, seedlings and transplants grown in pots in accordance with point 1.4. of Part I of Annex II to Regulation (EU) 2018/848 be labelled in-conversion?

This depends on the type of products.

Article 10 of Regulation (EU) 2018/848 provides for a conversion period to be respected and the conversion period is related to the cultivation of the plant on a given parcel (see point 1.7.1 of Part I of Annex II to Regulation (EU) 2018/848).

In accordance with Article 10(4) of Regulation (EU) 2018/848, a conversion period of at least 12 months must be complied with before the harvest of a food/feed product of plant origin containing only one agricultural crop ingredient can be labelled as “in conversion”. This does not therefore apply to ornamentals plants and which thus cannot be labelled in-conversion. In the case of edible herbs in pots (i.e. food), these herbs must be harvested from an in-conversion parcel that has completed a conversion of 12 months.

Seedlings and transplants (which are by definition PRM) can be labelled as “in conversion” under Article 10(4) of Regulation (EU) 2018/848, provided that a conversion period of 12 months has been respected. Again, the reference is to an in-conversion period linked to the parcel and the seedlings and transplants can therefore only be labelled “in-conversion” only if they have been harvested from a crop which had already fulfilled the conversion period of 12 months.

For seedlings which originate from seeds and could be grown in pots from the beginning, point 1.8.5.1 of Part I of Annex II to Regulation (EU) 2018/848 provides as follows: “*In addition, in case of a lack of availability of organic seedlings, “in-conversion seedlings”, marketed in compliance with Article 10(4), second subparagraph, point (a), may be used when grown as follows:*

- (a) through a cultivation cycle from seeds to final seedling lasting at least 12 months on a land parcel that, during that same period, has completed a conversion period of at least 12 months; or*
- (b) on an organic or in-conversion land parcel or in containers if covered by the derogation referred to in point 1.4, provided that the seedlings have originated from in-conversion seeds, harvested from a plant grown on a land parcel that has completed a conversion period of at least 12 months.’;*

This means that the seedlings must not be harvested before the 12 months conversion time are over.

18) Can a farmer use self-produced seedling if the farmer has received authorisation to use non-organic seeds according to point 1.8.5.1 of part I of Annex II to Regulation (EU) 2018/848 and has grown the seedlings in containers for further transplanting?

Yes. In cases of a lack of availability of organic or in-conversion seeds, farmers will need authorisation to use non-organic seeds to grow their own seedlings in accordance with the conditions set out under point 1.8.5.1 of Part I of Annex II to Regulation (EU) 2018/848. Production in containers is allowed pursuant to point 1.4(b) of Part I of Annex II to Regulation (EU) 2018/848, which reads as follows: “growing seedlings or transplants in containers for further transplanting”.

19) Can a nursery market seedlings of species that have a cultivation cycle completed in one growing season as organic seedlings if the nursery has received authorisation to use non-organic seeds according to point 1.8.6 of Part I of Annex II to Regulation (EU) 2018/848, and has grown the seedlings after sowing in compliance with all other relevant organic plant production requirements?

Yes. Nurseries producing and placing PRM on the market may be authorised by the competent authorities to produce organic seedlings under the conditions laid down in point 1.8.6 of Part I of Annex II to Regulation (EU) 2018/848 when mother plants or, where relevant, other plants intended for the production of PRM and produced in compliance with point 1.8.2 are not available in sufficient quantity or quality. The production must then comply with the organic production rules and in particular with the conditions set out in point 1.8.6.

20) How should the last paragraph of point 1.8.5.1. "...operators may use both organic and in-conversion plant propagating material taken from their own holding..." be read? Does this apply to land races as well as to catalogue varieties free of intellectual property rights?

Pursuant to point 1.8.5.1 of Part I of Annex II to Regulation (EU) 2018/848 and Article 6(i) of Regulation (EU) 2018/848, respect of horizontal rules is an *a priori* condition and farmers can use their own harvested seeds freely on their own holding under the conditions laid down in Article 14 of Regulation (EC) 2100/94. This covers all types of PRM, including land races.

First, the last paragraph of point 1.8.5.1 of Part I of Annex II to Regulation (EU) 2018/848 provides as follows: "*When in compliance with Article 6(i) operators may use both organic and in-conversion plant reproductive material obtained from their own holding*".

Second, Article 6(i) of Regulation (EU) 2018/848 provides that: "*Without prejudice to Article 14 of Regulation (EC) No 2100/94 and to the national plant variety rights granted under Member States' national law, the possibility for farmers to use plant reproductive material obtained from their own farms in order to foster genetic resources adapted to the special conditions of organic production*".

21) Can mushroom mycelium be produced organically?

Mushrooms are considered as plants for the purpose of the EU organic legislation. The mycelium is comparable to the vegetative parts of annual or perennial plants; while mushrooms are comparable to the reproductive parts of plants, like flowers and fruits.

The rules on plant production (Part I of Annex II to Regulation (EU) No 2018/848) and the specific rules regarding mushroom under point 2.1. of Part 1 of that annex must be respected for mushroom production. These rules apply to the entire fungal body, therefore including the mycelium and the mushrooms.

The conversion rules for plants and plant products set out in point 1.7. of Part 1 of Annex II to Regulation (EU) 2018/848 shall also apply to mushroom organic production. If fungus production (mycelium and mushrooms) is managed as an annual crop on the soil, a conversion period of at least two years is required before "sowing" i.e. the dispersal of spores in the soil/substrate or the grafting of the soil/substrate with mycelium. In case fungus production (mycelium and mushrooms) is managed as a perennial crop on the soil, a conversion period of at least three years has to be applied before the first harvest of organic mushrooms.

22) Can meristem culture be used in organic production?

Yes. However, meristem culture cannot be certified as organic in the multiplication of plants.

Point 1.8.4. of Part I of Annex II of Regulation (EU) 2018/848 lays down a specific provision concerning meristem culture as follows: "*1.8.4. For the production of organic varieties suitable for organic production, the organic breeding activities shall be conducted under organic conditions and shall focus on enhancement of genetic diversity, reliance on natural reproductive ability, as well as agronomic performance, disease resistance and adaptation to diverse local soil and climate conditions. All multiplication practices except meristem culture shall be carried out under certified organic management.*"

That provision, in itself, does not constitute a prohibition on the use of meristem culture. Because of the potentially long process of breeding for organic varieties, a meristem culture could be used, for example, to ensure that initial material is sanitised from viruses.

However, in the multiplication of plants, meristem culture cannot be certified as organic, because organic plant reproductive material to be used for the production of

organic products must be compliant with the provisions laid down under point 1.8.2 of Part I of Annex II of Regulation (EU) 2018/848.

Point 1.8.2. reads as follows: "*1.8.2. To obtain organic plant reproductive material to be used for the production of products other than plant reproductive material, the mother plant and, where relevant, other plants intended for plant reproductive material production shall have been produced in accordance with this Regulation for at least one generation, or, in the case of perennial crops, for at least one generation during two growing seasons.*"

23) Do organic wheat seeds have to be produced on fully converted land over two generations, when originating from conventional "mother plants"?

No. Wheat is a plant which has an annual cycle. One generation for the conventional mother plant is therefore sufficient in accordance with point 1.8.2 of Part I of Annex II to Regulation (EU) 2018/848, when wheat is produced on "fully organic converted land", i.e. the organic production rules must have been applied with respect to this land during a conversion period of at least two years before sowing.

The provisions of points 1.7.1 and 1.8.2 of Part I of Annex II to Regulation (EU) 2018/848 are relevant and provide as follows:

*"1.7.1. For plants and plant products to be considered as organic products, the production rules laid down in this Regulation **shall have been applied with respect to the parcels during a conversion period of at least two years before sowing** or, in the case of grassland or perennial forage, during a period of at least two years before its use as organic feed, or, in the case of perennial crops other than forage , **during a period of at least three years before the first harvest of organic products. (...)***

*1.8.2. To obtain organic plant reproductive material to be used for the production of products, other than plant reproductive material, the **mother plant and where relevant other plants intended for plant reproductive material production, shall have been produced in accordance with this Regulation for at least one generation**, or, in the case of perennial crops, for at least one generation during two growing seasons."*

Consequently, if a parcel has already been converted (2 years under organic rules as mentioned above), the mother plants that produce organic wheat seeds can be sown on that parcel and the harvested wheat seeds (after one generation, as wheat is an annual plant) can be placed on the market as organic, provided that all other relevant organic production rules are respected.

24) Must both the rootstocks and cuttings in a nursery be produced organically to produce an organic tree?

Yes.

The provisions of points 1.7.1, 1.8.2 and 1.8.6 of Part I of Annex II to Regulation (EU) 2018/848 are relevant and provide as follows:

*"1.7.1. For plants and plant products to be considered as organic products, the production rules laid down in this Regulation **shall have been applied with respect to the parcels during a conversion periods of at least two years before sowing** or, in the case of grassland or perennial forage, during a period of at least two years before its use as organic feed, or, in the case of perennial crops other than forage , **during a period of at least three years before the first harvest of organic products.***

(...)

*1.8.2. To obtain organic plant reproductive material to be used for the production of products, other than plant reproductive material, the **mother plant and where relevant other plants intended for plant reproductive material production, shall have been produced in accordance with this Regulation for at least one generation**, or, in the case of perennial crops, for at least one generation during two growing seasons.*

(...)

1.8.6. Competent authorities or, where appropriate, control authorities or control bodies recognised in accordance with Article 46(1) may authorise operators producing plant reproductive material for use in organic production to use non-organic plant reproductive material, when mother plants or, where relevant, other plants intended for the production of plant reproductive material and produced in compliance with point 1.8.2 are not available in sufficient quantity or quality, and to place such material on the market for use in organic production provided that the following conditions are met:

(a) the non-organic plant reproductive material used has not been treated after harvest with plant protection products other than those authorised in accordance with Article 24(1) of this Regulation, unless chemical treatment has been prescribed in accordance with Regulation (EU) 2016/2031 for phytosanitary purposes by the competent authorities of the Member State concerned for all varieties and heterogeneous material of a given species in the area in which the plant reproductive material is to be used. Where non-organic plant reproductive material treated with such prescribed chemical treatment is used, the land parcel on which the treated plant reproductive material is growing shall be subject, where appropriate, to a conversion period as provided in points 1.7.3 and 1.7.4;

(b) the non-organic plant reproductive material used is not a seedling of species that have a cultivation cycle completed in one growing season, from the transplantation of the seedling to the first harvest of product;

(c) the plant reproductive material is grown in compliance with all other relevant organic plant production requirements;

(d) the authorisation to use non-organic plant reproductive material shall be obtained before that material is sown or planted;

(e) the competent authority, control authority or control body responsible for the authorisation shall grant the authorisation only to individual users and for one season at a time, and shall list the quantities of the authorised plant reproductive material;

(f) by way of derogation from point (e), the competent authorities of the Member

States may annually grant a general authorisation for the use of a given species or subspecies or variety of non-organic plant reproductive material and make the list of species, subspecies or varieties publicly available and keep it updated on an annual basis. In that case, those competent authorities shall list the quantities of authorised non-organic plant reproductive material;

(g) the authorisations granted in accordance with this paragraph shall expire on 31 December 2036. By 30 June of each year, and for the first time by 30 June 2023, the competent authorities of the Member States shall notify the Commission and the other Member States of the information on the authorisations granted in accordance with the first paragraph.

Operators who produce and market the plant reproductive material produced in accordance with the first paragraph shall be allowed to make public, on a voluntary basis, the relevant specific information on the availability of such plant reproductive material in the national systems established in accordance with Article 26(2). Operators that opt to include such information shall ensure that the information is updated regularly, and is withdrawn from the national systems once the plant reproductive material is no longer available. When relying on the general authorisation referred to in point (f), operators shall keep records of the quantity used."

Consequently, given that rootstocks and cuttings are the "other plants intended for plant reproductive material production" pursuant to point 1.8.2 of Part I of Annex II to Regulation (EU) 2018/848, to produce an organic tree, both rootstock and cutting must be produced organically for at least two growing seasons.

When this is not possible, the nursery must be authorised to use such non-organic plant reproductive material under point 1.8.6 of Part I of Annex II to Regulation (EU) 2018/848 (please see also the reply to question 10 above).

25) Does point 1.8.6 of Part I of Annex II to Regulation (EU) 2018/848 apply to organic producers of seeds, such as cereals or leguminous seeds, who want to produce certified seed from basic seed²⁰? If yes, do those producers need to request authorisation to use conventional basic seed?

No, point 1.8.6 of Part I of Annex II to Regulation (EU) 2018/848 does not necessarily apply to organic producers of seeds such as cereals or leguminous seeds when they want to produce certified seed from basic seed.

The provisions of point 1.8.2 of Part I of Annex II to Regulation (EU) 2018/848 are relevant and provide as follows:

*"To obtain organic plant reproductive material to be used for the production of products, other than plant reproductive material, the **mother plant and where relevant other plants intended for plant reproductive material production, shall have been produced in accordance with this Regulation for at least one generation, or, in the case of perennial crops, for at least one generation during two growing seasons.**"*

Thus, for annual species of cereals and leguminosae, it is sufficient for the mother plant (one generation) to be grown organically by sowing conventional basic seed on an organic parcel to be able to harvest organic certified seeds. As for perennial species, the mother plant must be grown organically for two growing seasons in order to be able to harvest from it organic certified seed.

26) Does the term "plant reproductive material" in Regulation 2018/848 applies to seeds?

Yes, when seeds are intended to be placed on the market and to be used as plant reproductive material.

The definition of plant reproductive material of Article 3, point (17), of Regulation (EU) 2018/848 is relevant and provides that *"Plant reproductive material means plants and all parts of plants, **including seeds**, at any stage of growth that are capable of, and intended for, producing entire plants"*.

²⁰ The terms "certified seed" and "basic seed" refer to the categories established under the respective legislation on marketing of seeds (e.g. Article 2 of Council Directive 66/402/EEC of 14 June 1966 on the marketing of cereal seed)

27) When the non-organic seeds of an annual crop (like sunflowers) are sown under organic conditions, can their 'seedlings' be sold as 'organic' on the basis of an authorisation pursuant to point 1.8.6 of Part I of Annex II to Regulation (EU) 2018/848?

Yes, but under strict conditions.

First, an organic seedling to be used as plant reproductive material must derive from mother plants that meet the requirements of point 1.8.2 of Part I of Annex II to Regulation (EU) 2018/848:

*"1.8.2. To obtain organic plant reproductive material to be used for the production of products, other than plant reproductive material, the **mother plant and where relevant other plants intended for plant reproductive material production, shall have been produced in accordance with this Regulation for at least one generation**, or, in the case of perennial crops, for at least one generation during two growing seasons."*

Second, if the mother plants do not meet the requirements of point 1.8.2., the competent authority can authorise the use of non-organic seeds for the production of organic seedlings provided those seeds meet the requirements of point 1.8.6 of Part I of Annex II to Regulation (EU) 2018/848 (please see the reply to question 25 above).

28) Does the authorisation to use non-organic seedlings apply to vegetable seedlings where the growing season is less than 1 year?

No.

Points 1.8.5.8 and 1.8.6(b) of Part I of Annex II to Regulation (EU) 2018/848 are relevant and provide as follows:

"1.8.5.8. Competent authorities shall not authorise the use of non-organic seedlings in the case of seedlings of species that have a cultivation cycle completed in one growing season, from the transplantation of the seedling to the first harvest of product.

(...)

1.8.6. Competent authorities or, where appropriate, control authorities or control bodies recognised in accordance with Article 46(1) may authorise operators producing plant reproductive material for use in organic production to use non-organic plant reproductive material, when mother plants or, where relevant, other plants intended for the production of plant reproductive material and produced in compliance with point 1.8.2 are not available in sufficient quantity or quality, and to place such material on the market for use in organic production provided that the

*following conditions are met: (...) (b) **the non-organic plant reproductive material used is not a seedling of species that have a cultivation cycle completed in one growing season, from the transplantation of the seedling to the first harvest of product (...);***

Consequently, an authorisation for producers of plant reproductive material cannot be issued for seedlings when the cycle to reach the final product is just one growing season from the transplant of the seedling to the first harvest of the product. In such a case, producers must grow their own seedlings organically, starting from seeds.

29) Is it possible to put a non-organic seed from lettuce into 'organic' soil/substrate in pot, and to sell the small plant as organic to farmers?

Yes, but under strict conditions.

First, a nursery must start from seeds derived from a mother plant that has been organically grown pursuant to the requirements of point 1.8.2 of Part I of Annex II to Regulation (EU) 2018/848.

Second, if no organically grown mother plant is available, a nursery must be authorised to use non-organic seeds for the production of lettuce seedlings to be placed on the market as organic.

Third, it is possible to grow and market the seedling in a pot as it will be transplanted in compliance with the derogation under paragraph b of point 1.4. of Part I of Annex II to Regulation (EU) 2018/848.

Fourth, when a nursery cannot rely on seeds derived from organically grown mother plants in compliance with point 1.8.2 of Part I of Annex II to Regulation (EU) 2018/848, and when the nursery cannot produce the mother plant organically themselves, they must obtain an authorisation under point 1.8.6 of Part I of Annex II to Regulation (EU) 2018/848. Please see also the replies to questions 16 and 17 above.

30) Is it possible to give examples of which kind of species can fulfil the condition of point 1.8.6 (b) of Part I of Annex II to Regulation (EU) 2018/848?

Point 1.8.6(b) is relevant and provides the following: "*(b) the non-organic plant reproductive material used is not a seedling of species that have a cultivation cycle completed in one growing season, from the transplantation of the seedling to the first harvest of product (...)*".

Consequently, examples of species having a short cultivation cycle completed in one growing season and that can be reproduced via seedlings include lettuces, tomatoes, peppers, aubergines, zucchinis, etc.

31) Do the provisions of point 1.8.6 of Part I of Annex II to Regulation (EU) 2018/848 create false competition between PRM produced according to this point 1.8.6 and PRM “in-conversion to organic”?

No. Point 1.8.6 provides for a possible authorisation given by national authorities after an assessment of the situation on the ground. Such an authorisation is limited to operators, including nurseries, and can be granted when there is a technical impossibility to grow organic mother plants/other plants intended for the production of plant reproductive material in compliance with provisions of point 1.8.2.

By contrast, “in conversion” is related to the parcel and to in-conversion material derived from conventional or organic seeds. It is material grown for one year on an in-conversion parcel. “In conversion” PRM products are labelled differently because the parcel is still in-conversion.

32) What is the difference between point 1.8.5.1 (individual authorisation) of Part I of Annex II to Regulation (EU) 2018/848 point 1.8.5.7 (general authorisation) and point 1.8.6?

On the one hand, point 1.8.6 of Part I of Annex II to Regulation (EU) 2018/848 governs the production of plant reproductive material to be placed on the market as organic. It therefore concerns organic breeders/nurseries and provides that competent authorities **may** decide whether to delegate²¹ the power to issue such authorisations to control bodies.

On the other hand, points 1.8.5.1 and 1.8.5.7 govern possible derogations (individual or general) to be issued by the competent authorities to all operators to use non-organic conventional PRM for certain varieties or species to produce final organic products.

Please see further the replies to questions 8 and 20 above.

²¹ In case of delegations, the conditions set out in Chapter III of Regulation (EU) 2017/625 and Article 40 of Regulation (EU) 2018/848 must be satisfied.

33) Can organic farmers or “in conversion” farmers request authorisation for the use of non-organic plant reproductive material obtained on their own farms from separated units used for non-organic agriculture?

Yes. Farmers must obtain an authorisation because they will use self-produced non-organic seeds. However, if farmers decide to move to organic new parcels, they must respect the cycle of conversion of the new parcels in accordance with point 1.7 of Part I of Annex II to Regulation (EU) 2018/848, and the seeds produced after one year can be used as in-conversion seeds without the need to obtain an authorisation.

34) Must plant propagating material be accompanied by supporting documents from the supplier (e.g. invoice, quality document) or is it possible to use plant reproductive material on an organic farm, when this material has been bought on the free market (without relevant documents from the supplier)?

Yes.

When placed on the market, all plant reproductive material has to be labelled in compliance with the relevant EU horizontal marketing requirements (see [EU marketing requirements \(europa.eu\)](https://europe.eu)).

Moreover, the label of organic or in-conversion plant reproductive material must also comply with the relevant requirements of Regulation (EU) 2018/848.

Therefore, on an organic farm it is not possible to use plant reproductive material bought without a label as the organic farmer must be able to identify the appropriate plant reproductive material.

35) Is the authorisation received in one country valid to offer the material as “approved in accordance with point 1.8.6” in other EU countries?

Yes.

Plant reproductive material that meets the requirements of point 1.8.6 of Part I of Annex II to Regulation (EU) 2018/848 can, throughout the EU, be placed on the market and labelled as “organic”.

36) Can “organic PRM” produced on the basis of authorisation given by a Member State under point 1.8.6 of Part I of Annex II to Regulation (EU) 2018/848 be used in another Member State?

No. An authorisation under point 1.8.6. is to produce organic plant reproductive material in the territory of the Member State by the operator that obtains the authorisation.

Please see also above the reply to question 8 above.

37) Is grafting subject to the provisions relating to organic plant reproductive material ?

Yes.

Operators certified as organic must respect the applicable requirements of Regulation (EU) 2018/848, including point 1.8.2. of part I of Annex II to that regulation.

This is because the rootstock/graft or cuttings are “other plants intended for the production of plant reproductive material” within the meaning of point 1.8.6 of Part I of Annex II to Regulation (EU) 2018/848.

This is the reason why point 1.8.2 of Part I of Annex II to Regulation (EU) 2018/848 refers to *“where relevant” other plants intended for the production of plant reproductive material,*“:

*“To obtain organic plant reproductive material to be used for the production of products, other than plant reproductive material, the **mother plant and where relevant other plants intended for plant reproductive material production, shall have been produced in accordance with this Regulation for at least one generation, or, in the case of perennial crops, for at least one generation during two growing seasons.**”*

Indeed, in the case of grafting, “other plants” can be rootstocks and cuttings/scions that also be propagated and grown under organic conditions for either at least two growing seasons (in case of perennials) or at least one generation (in the case of non-perennials).

Please also see the reply to questions 9, 10 and 24 above.

4.3 Livestock production rules

1) Can I use milk replacers in organic production?

Point 1.4.1 (g) of Part II of Annex II to Regulation (EU) 2018/848 provides that "suckling mammals shall preferably be fed on maternal milk for a minimum period laid down by the Commission in accordance with point(a) of Article 14(3); milk replacers containing chemically synthesized components or components of plant origin shall not be used during that period".

Commission Implementing Regulation (EU) 2020/464 lays down minimum period for feeding animals with maternal milk for the different livestock species.

<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020R0464&from=EN>

2) Is it possible to produce organic insects in Europe? In particular for feeding organic poultry?

In principle, it is possible to produce insects for food and feed use but it has to be in compliance with EU food and feed safety horizontal rules.

The feeding related rules for the production of insects in the EU can be found in Regulation (EC) No 999/2001, Regulation (EC) No 183/2005, Regulation (EC) No 767/2009 and Regulation (EU) No 68/2013. These EU legal acts regulate the production of insects and products derived thereof, including the use of processed animal proteins (PAPs) in animal feed for food producing animals. The rules require that insects can be only fed with substrates that are authorised in the EU as feed materials for farmed animals. Therefore, catering waste or manure are substrates prohibited for insects raised in the EU.

Currently, products derived from insects, including PAPs originating from farmed insects, can be used in feed for aquaculture species, pigs and poultry pursuant to Regulations (EU) No 2017/893 and 2021/1372. Regulation (EU) No 2017/893 also establishes the list of insect species eligible for the production of processed insect proteins. Furthermore, Regulation (EU) No 2017/893 requires that the insects shall be fed with feed grade substrates. These requirements apply also to imported PAPs.

As regards live insects, while their use is not allowed as feed for ruminants, they can be used as feed for non-ruminant animals in accordance with entry 9.16.1 ('Terrestrial invertebrates, live') in Part C of the Annex to Regulation (EU) No 68/2013 and under the responsibility of the feed business operator placing the live insects on the market for their safety and under control of the competent authority in the respective Member State. Hence, live fly larvae could be used as feed for poultry subject to certain conditions as explained above.

The production of insects to be used as food is regulated under Regulation (EU) 2015/2283 on novel food, which is applicable since 1 January 2018. All insects must therefore be authorised under that regulation before they can be placed on the

market in the EU, including novel foods imported from third countries. The insect products authorised in the EU as a novel food can be found here: EUR-Lex - 02017R2470-20210627 - EN - EUR-Lex (europa.eu)

With respect to organic farming, live animals (including insects) are agricultural products within the scope of Article 2(1) (a) of Regulation (EU) No 2018/848, as they constitute live or unprocessed agricultural products, including seeds and other plant reproductive material. In addition, insects fall under the definition of livestock production as set out in Article 3(27) of Regulation (EU) 2018/848, which states that *'livestock production' means the production of domestic or domesticated terrestrial animals (including insects)*. However, at present, no specific rules exist for organic insect production other than bees.

Without prejudice to the rules for (conventional) production of live insects for feed, the general principles and the relevant rules with regard to organic livestock production have to be applied and according to Article 20 of Regulation (EU) 2018/848, for certain animal species in the absence of certain detailed production rules laid down at EU level, national rules may apply. Therefore, Member States have the possibility to lay down detailed production rules for the production of organic live insects such as fly larvae on their territory.

3) Can organic beekeepers harvest drone larvae for human consumption?

Live animals including drone larvae are listed in Annex I to the Treaty of the Functioning of the European Union (TFEU). They therefore constitute agricultural products falling within the scope of Regulation (EU) No 2018/848 under point (a) of Article 2(1) – live or unprocessed agricultural products.

As a consequence, a beekeeper producing drone larvae on the territory of a Member State will have to respect the provisions laid down under the EU organic legislation.

Moreover, drone larvae can be placed on the EU market as organic food, only after having been authorised under Regulation (EU) 2015/2283 on novel foods.

4) How is animal welfare taken into account in organic productions?

Regulation (EU) 2018/848 sets out the principles, objectives and overarching rules of organic production. In accordance with Article 4(e) of that regulation, organic production shall pursue the general objective of contributing to high animal welfare standards and in particular, to meeting the species-specific behavioural needs of animals.

Specific provisions applicable to livestock production are laid down in Part II of Annex II on livestock production and by Commission Implementing Regulation (EU) 2020/464.

Among others, point 1.7.7. and 1.7.8. of part II of Annex II provide that: *"Any suffering, pain and distress shall be avoided and shall be kept to a minimum during the entire life of the animal, including at the time of slaughter."* and *"Without prejudice to developments in Union legislation on animal welfare, tail-docking of sheep, beak trimming undertaken in the first three days of life, and dehorning may exceptionally be allowed, but only on a case-by-case basis and only when those practices improve the health, welfare or hygiene of the livestock or where workers' safety would otherwise be compromised. Disbudding may be allowed only on a case by case basis when it improves the health, welfare or hygiene of the livestock or where workers' safety would otherwise be compromised. The competent authority shall only authorise such operations where the operator has duly notified and justified the operations to that competent authority and where the operation is to be carried out by qualified personnel."*

Considering the provisions of Article 18 of Regulation (EC) 889/2008 related to the suffering of animals are comparable to provisions under Annex II Part II point 1.7.7. and 1.7.9 of Regulation (EU) 2018/848, *please see also the judgment of the Court of Justice in Case C-497/17 on the protection of animals at the time of killing available here:*

<http://curia.europa.eu/juris/documents.jsf?num=C-497/17>

The judgment concludes that the placing of the EU organic production logo is not authorised on products derived from animals which have been slaughtered in accordance with religious rites without first being stunned.

5) Which is the status of maximum residues levels (MRLs) for Dichlorodiphenyltrichloroethane (DDT) in animal fat from certified organic animals?

MRLs are set under Regulation (EC) No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin, and apply to all concerned commodities, with no differentiation between organic and conventional production.

There is no list of specific MRLs set for organic products at EU level.

In the case of DDT, this substance is not authorised in the EU for plant protection, but its persistency in the environment led to the need to set MRLs on the basis of a comprehensive consumer risk assessment.

You can find all MRLs set in the European Union, including those set in animal fat, at this web address: https://food.ec.europa.eu/plants/pesticides_en

6) Can non-organic animals be brought into an organic farm for breeding purpose?

Annex II Part II point 1.3.4. of Regulation (EU) 2018/848 provides for the possibility of bringing non-organic animals onto a farm for breeding purposes, subject to detailed conditions.

7) Can cows be tethered for a limited period during milking under organic rules?

Point 1.7.5. of part 2 of Annex II of Regulation (EU) No 2018/848 provides that *"tethering or isolation of livestock shall be prohibited, except in relation to individual animals for a limited period and insofar as this is justified for veterinary reasons. The isolation of livestock may only be authorised, and only for a limited period, where workers' safety is compromised or for animal welfare reasons. Competent authorities may authorise the tethering of cattle in farms with a maximum of 50 animals (excluding young stock) where it is not possible to keep the cattle in groups appropriate to their behaviour requirements, provided they have access to pastures during the grazing period, and have access to open air areas at least twice a week when grazing is not possible."*

8) Do Regulation (EU) 2018/848 apply to rabbits and rabbits' meat?

Yes. Organic rabbits and organic rabbit meat are covered by the scope of Regulation (EU) 2018/848. Article 2(1) states that the Regulation applies to *"live or unprocessed agricultural products" and "processed agricultural products for use as food"*.

Moreover, detailed production rules are laid down for rabbits under Annex II Part II point 1.9.5 of the same Regulation as well as under Commission Implementing Regulation (EU) 2020/464.

For processed organic rabbit meat for use as food, in addition to the general EU rules on food safety (Regulation (EC) No 178/2002), the specific provisions on organic processed food of Part IV of Annex II of Regulation (EU) 2018/848 apply.

9) Is boar taint vaccination compatible with organic production?

No. The use of boar taint vaccination is incompatible with organic certification under the rules laid down in point 1.5 of Part II of Annex II to Regulation (EU) 2018/848, which relate to health care. While Regulation (EU) 2018/848 does not allow the use of boar taint vaccination, point 1.7.10 of Part II of Annex II to Regulation (EU) 2018/848 does allow the use of physical castration at the most appropriate age by qualified personnel with adequate anaesthesia and/or analgesia in order to maintain the quality of products and traditional practices in organic production.

10) Can sand be used as exclusive litter in cubicles for pigs in organic production?

No. The requirements for litter for porcine animals are laid down in point 1.9.3.2 (b) of Part II of Annex II to Regulation (EU) 2018/848 which states:

"The housing shall be provided with a comfortable, clean and dry laying or rest area of sufficient size, consisting of a solid construction which is not slatted. Ample dry bedding strewn with litter material shall be provided in the rest area. The litter shall comprise straw or other suitable natural material. The litter may be improved and enriched with any mineral product authorised pursuant to Article 24 as a fertiliser or soil conditioner for use in organic production".

The word 'litter' covers straw or other plant matter used as bedding for animals.

11) How should the limit of 170 Kg/ha of organic nitrogen per year be applied?

For the reasons explained below, the limit of 170 Kg/ha shall be calculated by taking into account the total organic nitrogen coming from livestock manure spread on the total agricultural area of the farm per year.

First, point 1.6.6 of Part II of Annex II to Regulation 2018/848 provides that *"the total stocking density shall not exceed the limit of 170 Kg of organic nitrogen per*

year and hectare of agricultural area". Point 1.6.6 therefore refers to the total agricultural area and not only to the area actually available to the animals.

Second, point 1.9.8 of Part I of the same Annex II prohibits the use of mineral nitrogen fertiliser and point 1.9.4 establishes a limit applicable to the total content of nitrogen that can be present in organic fertilisers: *"The total amount of livestock manure, as defined in Directive 91/676/EEC, used in the in-conversion and organic production units shall not exceed 170 kg of nitrogen per year/hectare of agricultural area used. That limit shall only apply to the use of farmyard manure, dried farmyard manure and dehydrated poultry manure, composted animal excrement, including poultry manure, composted farmyard manure and liquid animal excrement."*

12) How could the open-air areas for poultry be managed?

The open air area should be managed in such a way that there is vegetation and it is attractive to the birds.

As laid down in Article 16(3) of Regulation (EU) 2020/464, *"Open air areas for poultry shall be mainly covered with vegetation composed of a diverse range of plants."* Article 16(4) of the same regulation sets out other requirements for open air areas and, among others, requires that open air areas should provide protective facilities or shrubs or trees to ensure the birds can use the whole area in a balanced way.

Consequently, while there is no prescribed minimum percentage of area to be covered by vegetation, the word "mainly" indicates that the major part shall be covered by a diverse range of plants.

13) How should the term "young poultry" be understood in relation to the potential derogation to use non-organic protein feed in poultry production?

The term "young poultry" should be understood as referring to the specific needs of young birds for certain amino acids for their growth.

First, point 1.9.4.2(c) of Part II of Annex II to Regulation (EU) 2018/848 refers to "young poultry" in the context of a possible derogation from the use of non-organic protein feed in poultry feed.

Second, while Regulation (EU) 2018/848 does not define the term "young poultry", as regards the production of *Gallus gallus* poultry, the definition can be deduced from the reference to Article 3(29) of Regulation (EU) 2018/848, which defines "pullets" as "young animals of the *Gallus gallus* species that are of an age of less than 18 weeks".

14) How should the requirements concerning grazing and access to pastures be read?

The requirements for grazing and access to pastures are mandatory for ruminants and equine animals in organic production because grazing and access to pastures allow animals to exercise and eat grass, which are beneficial for their welfare and nutrition.

However, Part II of Annex II to Regulation (EU) 2018/848 provides for a limited number of exceptions to the mandatory requirements for grazing and access to pastures.

First, in accordance with point 1.4.2.1 of Part II of Annex II to Regulation (EU) 2018/848, organic animals should graze on organic land, without prejudice to the exceptions set out in point 1.4.2.2 in case of grazing on common land and during the period of transhumance.

Second, point 1.7.3 of Part II of Annex II to Regulation (EU) 2018/848 states that *"Livestock shall have permanent access to open air areas that allow the animals to exercise, preferably pasture, whenever weather and seasonal conditions and the state of the ground allow, except where restrictions and obligations related to the protection of human and animal health have been imposed on the basis of Union legislation."*

Third, point 1.7.4 of Part II of Annex II to Regulation (EU) 2018/848 specifies that *"The number of livestock shall be limited with a view to minimising overgrazing, poaching of soil, erosion, and pollution caused by animals or by the spreading of their manure."*

Fourth, the rules on nutrition under point 1.9.1.1 of Part II of Annex II to Regulation (EU) 2018/848 state that *"(b) animals shall have access to pasturage for grazing whenever conditions allow; (c) notwithstanding point (b), male bovine animals over one year old shall have access to pasturage or an open air area; (d) where animals have access to pasturage during the grazing period and where the winter housing system allows the animals to move freely, the obligation to provide open air areas during the winter months may be waived. (e) rearing systems shall be based on maximum use of grazing pasturage, by reference to the availability of pastures in the different periods of the year;"*

By contrast, Part II of Annex II to Regulation (EU) 2018/848 does not provide for an exception to the mandatory requirements for grazing and access to pastures in relation to regarding permanent structural settings of the farms, such as the lack of organic pasture lands compared to the number of cattle kept on the farms or the presence of a road between the farms and the organic pasture lands.

15) When and how should the disbudding of small calves be authorised by Member State competent authorities?

Disbudding means the removal of the horn buds in calves when the actual horn is still absent or very small (< 2 cm), which generally includes animals up to 2 months of age. It is a mutilation that can cause stress and pain to the animals but is considered less stressful and painful than dehorning. Since one of the objectives of organic production is to contribute to high animal welfare standards, Regulation (EU) 2018/848 sets strict rules regarding the use of disbudding, laid down, in particular, in points 1.7.7, 1.7.8 and 1.7.9 of Part II of Annex II.

"1.7.7 Any suffering, pain and distress shall be avoided and shall be kept to a minimum during the entire life of the animal, including at the time of slaughter.

*1.7.8. Without prejudice to developments in Union legislation on animal welfare, tail docking of sheep, beak trimming undertaken in the first three days of life, and dehorning may exceptionally be allowed, but only on a case-by-case basis and only when those practices improve the health, welfare or hygiene of the livestock or where workers' safety would otherwise be compromised. Disbudding may be allowed only on a case by case basis when it improves the health, welfare or hygiene of the livestock or where workers' safety would otherwise be compromised. The competent **authority** shall only authorise such operations where the operator has duly notified and justified the operations to that competent authority and where the operation is to be carried out by qualified personnel.*

1.7.9. Any suffering to the animals shall be reduced to a minimum by applying adequate anaesthesia and/or analgesia and by carrying out each operation at only the most appropriate age by qualified personnel."

Based on these provisions, Member States competent authorities cannot grant "a general permission for disbudding". However, the wording of point 1.7.8 of Part II of Annex II (*only on a case-by-case basis*) allows, as a general rule, the grant of such permission on an overall farm basis since, in most cases, similar health, welfare, hygiene conditions or risks for workers' safety will exist on a given farm.

Finally, the requirement in point 1.7.8 that "[t]he competent authority shall only authorise such operations where the operator has duly notified and justified the operations to that competent authority" requires the Member State competent authorities to regularly review an authorisation. In particular, an operator should notify to the relevant competent authority on at least an annual basis why these operations are justified.

16) Is it possible for a farm to have several organic production units with fattening poultry on one site?

No. Several fattening poultry houses on one site - even if all necessary facilities including electricity and water supply are separated - cannot be considered as

separated organic production units. This is because an organic production unit, as defined in Article 3(9) of Regulation (EU) 2018/848, includes not only the poultry houses themselves but also the primary production premises, land parcels, open air areas, premises for the storage of crops, of crops products, of animal products, of raw materials and of any relevant inputs.

Furthermore, an organic production unit with several poultry houses shall comply with the maximum total usable surface area of 1 600 m² for fattening poultry set out in point 1.9.4.4 (m) of Part II of Annex II to Regulation (EU) 2018/848.

17) Can livestock such as beef or dairy cattle be kept tethered all the time in organic production?

No. Under point 1.7.5 of Part II of Annex II of Regulation 2018/848, tethering of livestock is prohibited in organic production except in relation to individual animals for a limited period and insofar as this is justified for veterinary reasons.

However, point 1.7.5 of Part II of Annex II of Regulation 2018/848 also provides that tethering of livestock is possible in organic production, albeit under certain strict conditions and only if allowed by the competent authorities. In that regard, point 1.7.5 also allows the competent authorities to authorise the tethering of cattle in farms with a maximum of 50 adult animals if it is not possible to keep cattle in groups appropriate to their behaviour requirements. This authorisation can be granted only if cattle have access to pastures during the grazing period, and have access to open air areas at least twice a week when grazing is not possible.

18) How should the cooperation agreement with respect to organic manure spreading be implemented?

Organic farmers producing livestock must ensure that they have sufficient organic agricultural land to dispose of the manure produced by their livestock while respecting the maximum limit of 170 kg of organic nitrogen per year and hectare set in points 1.6.6 and 1.6.7 of Annex II, Part II of Regulation (EU) 2018/848.

If organic farmers do not have enough land, they must establish a written cooperation agreement with another farmer in accordance with point 1.1 of Annex II, Part II of Regulation (EU) 2018/848.

The manure produced by organic livestock on the farm should be used within the limits set out in point 1.9.4 of Annex I, Part I of Regulation (EU) 2018/848.

The remaining manure should be considered as “surplus” and farmers can establish a written agreement with another farmer complying with organic production rules in

order to spread this surplus manure. In such a case, the maximum limit of 170 kg of organic nitrogen per year and hectare is calculated on all the organic production units, including those covered by cooperation agreements.

19) Is the presence of a veranda obligatory for breeding organic birds and pullets)?

No. While Regulation (EU) 2018/848 does not require the presence of a veranda, point 1.9.4.4 (f) of Part II of Annex II to the Regulation allows organic producers of breeding birds or pullets that have a veranda to have this veranda considered as an open-air area in case of avian influenza outbreaks: *"by way of derogation from point 1.6.5, in the case of breeding birds and pullets aged under 18 weeks, when the conditions specified in point 1.7.3 as regards restrictions and obligations related to the protection of human and animal health imposed on the basis of Union legislation are met and prevent breeding birds and pullets aged under 18 weeks from having access to open air areas, verandas shall be considered as open air areas and, in such cases, shall have a wire mesh barrier to keep other birds out"*

20) Can non-organic pullets be introduced in an organic holding of laying hens?

Yes, but under strict and limited conditions.

On the one hand, for poultry, organic livestock must be born or hatched and raised in organic production units without prejudice to the rules on conversion (see point 1.3.1 of Part II of Annex II to Regulation (EU) 2018/848).

On the other hand, Regulation (EU) 2018/848 also provides for possible derogations to introduce non-organic animals into an organic holding. For example, where a flock is constituted for the first time, or is renewed or reconstituted, and where the qualitative and quantitative needs of farmers cannot be met, the competent authority may decide that non-organically reared poultry may be brought into an organic poultry production unit, provided that the pullets for the production of eggs and poultry for meat production are less than three days old (see point 1.3.4.3 of Part II of Annex II to Regulation (EU) 2018/848).

Products derived from non-organic animals may only be considered as organic after a conversion period (see point 1.3.4.3 of Part II of Annex II to Regulation (EU) 2018/848). Point 1.2.2(e) of Part II of Annex II to Regulation (EU) 2018/848 related to conversion sets the conversion periods specific to laying hens as follows *"six weeks in the case of poultry for egg production brought in before they are three days old"*.

21) Can organic and non-organic grazing areas be present on the same organic farm?

Yes, but under strict conditions.

Articles 9(2) and 9(7), points (a) and (b), of Regulation (EU) 2018/848 state *that "the entire holding shall be managed in compliance with the requirements of this Regulation that apply to organic production" and that "notwithstanding paragraph 2, a holding may be split into clearly and effectively separated production units for organic, in-conversion and non-organic production, provided that the non-organic production unit:*

a) as regards livestock, different species are involved;

b) as regards plants, different varieties that can be easily differentiated are involved."

Moreover, Article 3(9) of Regulation (EU) 2018/848 defines "production unit" as *"all assets of a holding, such as primary production premises, land parcels, pasturages, open air areas, livestock buildings or parts thereof, hives, fish ponds, containment systems and sites for algae or aquaculture animals, rearing units, shore or seabed concessions, and premises for the storage of crops, of crop products, of algae products, of animal products, of raw materials and of any other relevant inputs managed as described in point (10), point (11) or point (12);"*

Grazing parcels are therefore part of the production unit and, when managed organically or conventionally, they must be clearly and effectively separated in different organic and non-organic production units, and the non-perennial crops must be of different varieties that can be easily differentiated. In the case of perennial crops, and pursuant to Article 9(8) of Regulation (EU) 2018/848, it is not only the same species, but also the same variety, that can be grown in the same holding when split into clear and effective separate production units: *"By way of derogation from point (b) of paragraph 7, in the case of perennial crops which require a cultivation period of at least three years, different varieties that cannot be easily differentiated, or the same varieties, may be involved, provided that the production in question is within the context of a conversion plan, and provided that the conversion of the last part of the area related to the production in question to organic production begins as soon as possible and is completed within a maximum of five years."* In this last case, the production must therefore be subject to a conversion plan to be completed within a maximum of 5 years and under the specific conditions laid down in points (a), (b) and (c) of Article 9(8): *"In such cases:*

(a) the farmer shall notify the competent authority, or, where appropriate, the control authority or the control body, of the start of harvest of each of the products concerned at least 48 hours in advance;

(b) upon completion of the harvest, the farmer shall inform the competent authority, or, where appropriate, the control authority or the control body, of the exact quantities harvested from the units concerned and of the measures taken to separate the products;

(c) the conversion plan and the measures to be taken to ensure the effective and clear separation shall be confirmed each year by the competent authority, or, where appropriate, by the control authority or the control body, after the start of the conversion plan."

22) What is the meaning of "veterinary reasons", which can permit the use of restricted feeding?

Annex II Part II point 1.4.1. (b) of Regulation (EU) 2018/848 provides that: *"livestock shall be fed with organic or in-conversion feed that meets the animal's nutritional requirements at the various stages of its development; restricted feeding shall not be permitted in livestock production unless justified for veterinary reasons;"*.

Veterinary reasons therefore mean that restricted feeding is necessary for animal health and for the welfare of the animals and not for the purposes of enhancing reproductive performances.

23) What is the notion of "animal species" under Article 9 of Regulation (EU) 2018/848?

The notion of "animal species" under Article 9 of Regulation (EU) 2018/848 has the same meaning as in biology: *"a group of living organisms consisting of similar individuals capable of exchanging genes or interbreeding. The species is the principal natural taxonomic unit, ranking below a genus and denoted by a Latin binomial ²², e.g. Gallus gallus"*.

As for the term "species" in relation to livestock, it is used in several different provisions of Regulations (EU) 2018/848 and (EU) 2020/464.

First, Article 9(2) of Regulation (EU) 2018/848 provides that *"The entire holding shall be managed in compliance with the requirements of this Regulation that apply to organic production" and its paragraph 7 sets a derogation allowing parallel production under certain strict conditions "Notwithstanding paragraph 2, a holding may be split into clearly and effectively separated production units for organic, in-conversion and non-organic production, provided that for the non-organic production units: (a) as regards livestock, different species are involved."*

²² Oxford Dictionary

Second, recital (19) of Regulation (EU) 2018/848 provides the following explanation regarding the provisions on parallel production set out in Article 9 of that Regulation: *"The risk of non-compliance with organic production rules is considered higher in agricultural holdings which include units that are not managed under those rules. Therefore, after an appropriate conversion period, all agricultural holdings in the Union which aim to become organic should be entirely managed in compliance with the requirements applicable to organic production. However, holdings including both units managed under organic production rules and units managed under non-organic production rules should be allowed under certain conditions, including **in particular the condition of clear and effective separation between organic, in-conversion and non-organic production units and between the products produced by those units.**"*

24) Would the practices of dehorning and disbudding of animals be possible in organic livestock rearing?

Yes, but only under strict and limited conditions.

Dehorning and disbudding are not equivalent in terms of the risks for animal welfare. Dehorning is usually considered riskier as it is performed when animals are older (and the horns are therefore already grown).

Point 1.7.8 of Part II of Annex II to Regulation (EU) 2018/848 regarding mutilations states the following: *"Without prejudice to developments in Union legislation on animal welfare, tail-docking of sheep, beak trimming undertaken in the first three days of life, and dehorning may exceptionally be allowed, but only on a case by-case basis and only when those practices improve the health, welfare or hygiene of the livestock or where workers' safety would otherwise be compromised. Disbudding may be allowed only on a case-by-case basis when it improves the health, welfare or hygiene of the livestock or where workers' safety would otherwise be compromised. The competent authority shall only authorise such operations where the operator has duly notified and justified the operations to that competent authority and where the operation is to be carried out by qualified personnel".*

25) Would it be possible to introduce non-organic animals into an organic farm?

Yes, but under strict and limited conditions.

On the one hand, organic livestock must be born or hatched and raised in organic production units without prejudice to the rules on conversion (see point 1.3.1 of Part II of Annex II to Regulation (EU) 2018/848).

On the other hand, Regulation (EU) 2018/848 also provides for possible derogations to introduce non-organic animals into an organic holding. In particular, point 1.3.4.1 of Part II of Annex II to Regulation (EU) 2018/848 provides as follows: *"By way of derogation from point 1.3.1, for breeding purposes, **non-organically raised animals may be brought to an organic production unit when breeds are in danger of being lost to farming** as referred to in point (b) of Article 28(10) of Regulation (EU) No 1305/2013 and acts adopted on the basis thereof. In such case, the animals of those breeds need not necessarily be nulliparous".*

The conditions for breeds to be considered as in danger of being lost to farming are further set out in Commission Delegated Regulation (EU) No 807/2014 of 11 March 2014 supplementing Regulation (EU) No 1305/2013. In accordance with point 1.3.4.5 of Part II of Annex II of Regulation (EU) 2018/848, the operator must keep records or documentary evidence of the origin of the animals. Part II of Annex II of Regulation (EU) 2018/848 also contains the other following derogations allowing the introduction of non-organic young animals and non-organic adult animals into an organic holding:

*"1.3.4.4.1. For breeding purposes, **non-organic young animals may be introduced when a herd or flock is constituted for the first time**. They shall be reared in accordance with the organic production rules immediately after they are weaned. In addition, the following restrictions shall apply on the date on which those animals enter the herd or flock: (a) bovine animals, equine animals and cervine animals shall be less than six months old; (b) ovine animals and caprine animals shall be less than 60 days old; (c) porcine animals shall weigh less than 35 kg; (d) rabbits shall be less than three months old."* (Point 1.3.4.4.1 of Part II of Annex II of Regulation (EU) 2018/848).

*"1.3.4.4.2. For breeding purposes, **non-organic adult male and non-organic nulliparous female animals may be introduced for the renewal of a herd or flock**. They shall be reared subsequently in accordance with the organic production rules. In addition, the number of female animals shall be subject to the following restrictions per year: up to a maximum of 10 % of adult equine animals or bovine animals and 20 % of the adult porcine animals, ovine animals, caprine animals, rabbits or cervine animals may be introduced; for units with fewer than 10 equine animals, cervine animals or bovine animals or rabbits, or with fewer than five porcine animals, ovine animals or caprine animals, any such renewal shall be limited to a maximum of one animal per year."*

"1.3.4.4.3. The percentages set in point 1.3.4.4.2 may be increased up to 40 %, provided that the competent authority has confirmed that any of following conditions is fulfilled: (a) a major extension to the farm has been undertaken (b) one breed has been replaced with another; (c) a new livestock specialisation has been initiated."

The constitution of a herd for the first time is considered as similar to the condition that *"a new livestock specialisation has been initiated"*. The percentages set out in point 1.3.4.4.2 can therefore be increased to up to 40% for non-organic nulliparous female animals.

26) Can beeswax be used as an input in organic production?

Yes.

Beeswax is listed in Annex I of Regulation (EU) 2018/848. Pursuant to Article 2(1) of that Regulation, the EU organic production rules therefore apply to that product. This is because Article 2(1) of Regulation (EU) 2018/848 provides that the regulation *"also applies to certain other products closely linked to agriculture listed in Annex I to this Regulation"*.

Since the date of application of Regulation (EU) 2018/848, i.e. 1 January 2022, beeswax can be certified as organic, subject to the respect of all applicable provisions, and it can be used as an input in organic beekeeping

Particular attention should be paid to the specific conversion rules applicable to this product and to the rules on housing and husbandry practice.

First, point 1.2.2 of Part II of Annex II to Regulation (EU) 2018/848 provides as follows:

"Conversion periods specific to the type of animal production are set out as follows: (...)

(f) 12 months for bees.

During the conversion period, the wax shall be replaced with wax coming from organic beekeeping. However, non-organic beeswax may be used:

(i) where beeswax from organic beekeeping is not available on the market

(ii) where it is proven free of contamination with products or substances not authorised for use in organic production; and (iii) provided that it comes from the cap; the beeswax for new foundations shall come from organic production units;"

Second, point 1.9.6.5, point (e), of Part II of Annex II to Regulation (EU) 2018/848 provides that *"the beeswax for new foundations shall come from organic production units"*.

Organic beeswax is also an input in organic production, and is listed in Annex V to Commission Implementing Regulation (EU) 2021/1165:

- in section A1 as a food additive -E 901- that can be used as a confectionery glazing agent only when coming from organic production; and
- in section A2 as a processing aid authorised as a releasing agent for products of plant origin only when coming from organic production.

27) Is it possible to certify horses for leisure or sports as organic?

Yes.

Horses are listed as live animals in Chapter I of Annex I of the Treaty on the Functioning of the European Union (TFEU). Pursuant to Article 2(1)(a) of that Regulation, the EU organic production rules therefore apply to agricultural products from horses:

"This Regulation applies to the following products originating from agriculture, including aquaculture and beekeeping, as listed in Annex I to the TFEU and to products originating from those products, where such products are, or are intended to be, produced, prepared, labelled, distributed, placed on the market, imported into or exported from the Union: (a) live or unprocessed agricultural products, including seeds and other plant reproductive material;[...]"

In addition, under Article 3, point (27), of Regulation (EU) 2018/848, *"livestock production means the production of domestic or domesticated terrestrial animals"*.

It is therefore possible to certify live horses for leisure or sports as organic animals, provided that the rules relevant to the organic production of livestock and the EU horizontal legislation are met.

28) What should be understood as natural grazing to grow organic deer?

"Natural grazing" refers to farmland for grazing.

Point 1.9.2.1 (f) of Part II of Annex II to Regulation (EU) 2018/848 relates to the nutrition of cervine animals and provides as follows:

"(f) natural grazing shall be ensured in a pen during the period of vegetation. Pens that cannot provide feed by grazing during the period of vegetation shall not be allowed;"

That provision should be read together with the provisions of point 1.9.2.1 (b), (c), and (g) of Part II of Annex II to Regulation (EU) 2018/848, which provide the following:

"(b) animals shall have access to pasturage for grazing whenever conditions allow;"

(c) where animals have access to pasturage during the grazing period and where the winter housing system allows the animals to move freely, the obligation to provide open air areas during the winter months may be waived;"

(d) rearing systems shall be based on maximum use of grazing pasturage by reference to the availability of pastures in the different periods of the year;"

(g) feeding shall only be allowed in the event of a shortage of grazing due to poor weather conditions;"

29) Which rules apply to determine the flock size for compartment for brother roosters in organic production?

Article 15(3), point (b), of Commission Implementing Regulation (EU) 2020/464 establishes rules governing the maximum flock sizes in a single compartment of a poultry house. For fattening poultry *Gallus gallus*, the maximum flock size is 4800 animals.

Consequently, once pullets have been sexed and are raised as brother roosters (as defined in Article 13, point (c), of Regulation (EU) 2020/464), the maximum flock size of the compartment must therefore be limited to 4800 brother roosters.

4.4. Aquaculture production rules: algae and aquatic animals

1) Can a production made with indoor aquaponics systems be certified organic?

Aquaponics is a type of hydroponics which according to point 1.2. of Part 1 of Annex II of Regulation (EU) 2018/848 is a cultivation system which is not allowed in the organic production of plants not naturally growing in water. Thus, plants not naturally growing in water produced through aquaponics systems cannot be certified as organic.

On the other hand, the use of aquaponics systems for producing aquaculture animals is not prohibited by Regulation (EU) 2018/848. Therefore, the production of fish in facilities using aquaponics systems could be considered as organic only when done in compliance with the production rules set out in Part 3 of Annex II of Regulation (EU) No 2018/848. In order to ascertain if it is possible to certify your products as organic, you should approach a control body in your Member State.

A list of the control bodies in each Member State is available at:

https://ec.europa.eu/agriculture/ofis_public/index.html

2) Is it possible to use insect meal in organic aquaculture?

Since July 2017 it is possible, pursuant to Regulation (EU) No 2017/893, to use processed animal proteins (PAPs) from insects in conventional aquaculture, provided that they are produced according to the requirements established in that regulation, including as regards the feed for the insects (no waste can be used as substrate for the insects).

However, in organic aquaculture, it is not possible to use insect products as non-organic feed ingredients, because these are not listed as feed in Commission Implementing Regulation (EU) 2021/1165. Insects are considered livestock, so in principle, they can be produced organically. In that case, they can be used when produced organically under the category "organic feed materials of plant or animal origin" referred to in point 3.1.3.3. of Part 3 of Annex II to Regulation (EU) 2018/848.

At present, no detailed organic production rules for insects have been developed and approved, either at EU or at national level. Therefore, there are currently no possibilities to feed organic shrimps or fish with organic or non-organic insect products.

3) Can hormones and hormones derivatives be used in organic aquaculture?

No. Under point 3.1.2.2. of Part 3 of Annex II to Regulation (EU) 2018/848, the use of hormones and hormone-derivates for breeding purposes of all species of aquaculture is prohibited. For example, in the case of organic caviar, it has to be produced without using hormones and hormone derivatives.

4) Can non-organic juveniles be used for breeding purposes in organic aquaculture?

Yes, but subject to certain conditions as Regulation (EU) 2018/848 requires Member States to issue an authorisation for the use of non-organic juveniles for breeding purposes.

Such an authorisation is to be granted based on a case by case assessment, as Point 3.1.2.1(d) of Part III of Annex II provides that: *"for breeding purposes, wild-caught or non-organic aquaculture animals may be brought into a holding only in duly justified cases where no organic breed is available or where new genetic stock for breeding purposes is brought into the production unit after an authorisation has been granted by the competent authority with a view to improving the suitability of genetic stock. Such animals shall be kept under organic management for at least three months before they may be used for breeding"*.

5) Can non-organic juveniles be used for on-growing purposes in organic aquaculture?

Yes, but subject to certain strict conditions as Regulation (EU) 2018/848 requires Member States to issue an authorisation for the use of non-organic juveniles for on-growing purposes.

Such an authorisation is to be granted based on a case by case assessment, pursuant to point 3.1.2.1(e) of Part III of Annex II to Regulation (EU) 2018/848: *"Member States may authorise the introduction for on-growing purposes on an organic production unit of a maximum of 50 % of **non-organic juveniles of species that were not developed as organic in the Union by 1 January 2022**, provided that at least the latter two thirds of the duration of the production cycle are managed under organic management. Such derogation may be granted for a maximum period of two years and shall not be renewable"*.

6) What the species can be subject to possible derogations for use of non-organic juveniles for on-growing purposes in organic aquaculture?

Derogations shall be limited to species which were not developed as organic in the Union by 1 January 2022 and therefore species not yet included in Annex II of Commission Implementing Regulation (EU) 2020/464.

Point 3.1.2.1(e) of Part III of Annex II to Regulation (EU) 2018/848 provides that: *"By way of derogation from point (a), Member States may authorise the introduction for on-growing purposes on an organic production unit of a maximum of 50 % of non-organic juveniles of species that were not developed as organic in the Union by 1 January 2022, provided that at least the latter two thirds of the duration of the*

production cycle are managed under organic management. Such derogation may be granted for a maximum period of two years and shall not be renewable".

7) Can closed recirculation aquaculture systems be used in the production of salmon smolts?

Yes. In accordance with Annex II Part III Point 3.1.5.1 of Regulation (EU) 2018/848: *"Closed recirculation aquaculture animal production facilities shall be prohibited, with the exception of hatcheries and nurseries or facilities for the production of species used for organic feed organisms."*

The definition of nursery is provided by Article 3, point (37), of Regulation (EU) 2018/848: *"'nursery' means a place where an intermediate aquaculture production system is applied between the hatchery and grow-out stages. The nursery stage is completed within the first third of the production cycle, with the exception of species undergoing a smoltification process"*.

The definition of nursery does not exclude those species undergoing a smoltification process; rather, it specifies that the duration of the nursery stage in cases of species undergoing the smoltification process may be longer than the first third of the production cycle. Smoltification is therefore clearly considered part of the nursery stage.

8) How should the provisions be read concerning the quality of water for organic bivalves?

Annex II, Part III, point 3.1.3.2(b) of Regulation (EU) 2018/848 provides for the requirements for the areas suitable for organic production of bivalve molluscs and other species that are not fed by man but instead feed on natural plankton as follows: *"with regard to bivalve molluscs and other species which are not fed by man but instead feed on natural plankton, the following rules shall apply: ...(b)the growing areas shall be suitable from a health point of view and shall either be of high ecological status as defined by Directive 2000/60/EC or of good environmental status as defined by Directive 2008/56/EC3 or of equivalent quality to:*

- *the production zones classed as A in Regulation (EC) No 854/2004, until 13 December 2019, or*
- *the corresponding classification areas set out in the implementing acts adopted by the Commission in accordance with Article 18(8) of Regulation (EU) 2017/625, from 14 December 2019."*

The main differences between conventional and organic production are the prohibition to use artificially induced polyploid animals and the quality of water in the zone in which the molluscs are harvested.

Member States shall determine whether a "growing area" is suitable from a health point of view for the production of shellfish and then verify whether those growing areas identified as safe comply with at least one of the three categories below:

- are of high ecological status under the Directive 2000/60/EC (Water Framework Directive); or
- are of good environmental status under the Directive 2008/56/EC (Marine Strategy Framework Directive); or
- are of equivalent quality to zone A of Regulation (EU) 2019/627.

The criteria are not additional as it is evident from the use of "or".

9) What are the requirements for the production of organic micro-algae?

The requirements for the production of organic micro-algae are the same as for organic algae apply.

Regulation (EU) 2018/848 refers to algae and under its Annex II part III point 2 concerning requirements for algae provides for the following: *"In addition to the general production rules laid down in Articles 9, 10, 11 and 15, and where relevant in Section 1 of this Part, the rules laid down in this Section shall apply to the organic collection and production of algae. Those rules shall apply mutatis mutandis to the production of phytoplankton."*

Moreover, pursuant to European Standard EN 17399:2020²³ on algae and algae products, algae include micro-algae because algae are regarded as a functional group of organisms consisting of microalgae, macroalgae, cyanobacteria and Labyrinthulomycetes.

10) Can closed recirculation aquaculture systems be used in organic production?

The use of closed recirculation systems in organic production is prohibited, subject to certain specific exceptions.

A definition of closed recirculation aquaculture facility is provided for in Article 3, point (34), of Regulation (EU) 2018/848: *"closed recirculation aquaculture facility" means a facility where on land or in a vessel aquaculture takes place within an enclosed environment involving the recirculation of water and which depends on permanent external energy input to stabilize the environment for the aquaculture animals".*

In accordance with Annex II Part III Point 3.1.5.1 of Regulation (EU) 2018/848: *"Closed recirculation aquaculture animal production facilities shall be prohibited, with*

²³ EU Standards available here: BS EN 17399:2020 Algae and algae products. Terms and definitions-European Standards ([en-standard.eu](https://www.en-standard.eu))

the exception of hatcheries and nurseries or facilities for the production of species used for organic feed organisms.”

The definition of nursery is provided by Article 3, point (37), of Regulation (EU) 2018/848: “*‘nursery’ means a place where an intermediate aquaculture production system is applied between the hatchery and grow-out stages. The nursery stage is completed within the first third of the production cycle, with the exception of species undergoing a smoltification process*”.

Smoltification is the parr-smolt transformation occurring in species like salmon.²⁴

The possible use of a closed recirculation aquaculture system is limited to facilities producing organic feed and to hatcheries and nurseries which, for most species, cover the first third of the life cycle of the aquaculture animals.

However, when smoltification occurs, the possible use of a closed recirculation aquaculture system in nursery can last longer than the first third of the life cycle of the aquaculture animals because the nursery stage is not completed in one third of the production cycle.

11) *How should the production of organic broodstock be managed?*

Organic broodstock shall be reared in compliance with all the relevant principles, objectives and requirements for organic aquaculture under Regulation (EU) 2018/848.

First, point 3.1.2.1(a) of Part III of Annex II requires that “*organic aquaculture shall be based on the rearing of young stock originating from organic broodstock and from organic production units*”.

Second, point 3.1.6.2. of Part III of Annex II provides that “[t]he handling of aquaculture animals shall be minimised, and shall be undertaken with the greatest care. Proper equipment and protocols shall be used to avoid stress and physical damage associated with handling procedures. Broodstock shall be handled in such a manner as to minimise physical damage and stress, and shall be handled under anaesthesia where appropriate. Grading operations shall be kept to a minimum and shall only be used where required to ensure fish welfare.”

²⁴ Animal welfare aspects of husbandry systems for farmed Atlantic salmon – Scientific Opinion of the Panel on Animal Health and Welfare – EFSA Journal (2008) 736,1-31.

12) What conversion period should apply for hatcheries and nurseries when they can be drained, cleaned and disinfected?

A conversion period of six months applies for hatcheries and nurseries when they can be drained, cleaned and disinfected.

Annex II, Part III, Point 3.1.1 of Regulation (EU) 2018/848 provides for the following conversion periods:

“(a) for facilities that cannot be drained, cleaned and disinfected, a conversion period of 24 months;

(b) for facilities that have been drained, or fallowed, a conversion period of 12 months;

(c) for facilities that have been drained, cleaned and disinfected a conversion period of six months;

(d) for open water facilities, including those farming bivalve molluscs, a conversion period of three months.”.

Under the definition of ‘production unit’, which is laid down in Article 3, point (9) of Regulation (EU) 2018/848, “‘production unit’ means all assets of a holding, such as primary production premises, land parcels, pasturages, open air areas, livestock buildings or parts thereof, hives, fish ponds, containment systems and sites for algae or aquaculture animals, rearing units, shore or seabed concessions, and premises for the storage of crops, of crop products, of algae products, of animal products, of raw materials and of any other relevant inputs managed as described in point (10), point (11) or point (12)”.

Against this background, hatcheries and nurseries are a possible asset of the ‘production unit’ and the conversion period should therefore apply to hatcheries and nurseries.

13) What is the meaning of the term “pinching” in the provisions of point 3.1.6.8. of part III to Annex II to Regulation (EU) 2018/848 related to animal welfare in the aquaculture sector?

Point 3.1.6.8 of Part III of Annex II to Regulation (EU) 2018/848 reads as follows: “*Eyestalk ablation, including all similar practices such as ligation, incision and pinching, is prohibited.*”

The term “pinching” is one of the possible practices, such as ablation, ligation, or incision, to eliminate the flow of hormones in female crustaceans and to induce ovarian development.

14) Could a non-organic aquaculture product be labelled as “organic fed” when completely fed with organic feed?

No. Articles 30(1) and (2) of Regulation (EU) 2018/848 provide as follows:

“(1) For the purposes of this Regulation, a product shall be regarded as bearing terms referring to organic production where, in the labelling, advertising material or commercial documents, such a product, its ingredients or feed materials used for its production are described in terms suggesting to the purchaser that the product, ingredients or feed materials have been produced in accordance with this Regulation. In particular, the terms listed in Annex IV and their derivatives and diminutives, such as ‘bio’ and ‘eco’, whether alone or in combination, may be used throughout the Union and in any language listed in that Annex for the labelling and advertising of products referred to in Article 2(1) which comply with this Regulation.

(2) For the products referred to in Article 2(1), the terms referred to in paragraph 1 of this Article shall not be used anywhere in the Union, in any language listed in Annex IV, for the labelling, advertising material or commercial documents of a product which does not comply with this Regulation.

Furthermore, no terms, including terms used in trademarks or company names, or practices shall be used in labelling or advertising if they are liable to mislead the consumer or user by suggesting that a product or its ingredients comply with this Regulation.”

In light of those provisions, the term “organic” cannot be used for a product which does not comply with organic Regulation (EU) 2018/848.

This is because the use of the term “organic” for an aquaculture animal – fed with organic feed but not produced in accordance with all the applicable organic production rules, including origin of the animals, conversion rules, and healthcare - would potentially mislead consumers.

15) Which techniques for hybridisation are prohibited in organic aquaculture?

While Regulation (EU) No 2018/848 does not contain a definition of artificial hybridisation, it can be deduced from its provisions that any technique used to induce hybridisation that would not naturally occur must be considered artificial and

is prohibited in organic production (including techniques using hormones or in-vitro fertilisation).

The relevant provisions of Regulation (EU) No 2018/848 are the following.

First, Article 5 of Regulation (EU) No 2018/848 establishes the following general principles of organic production:

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

(i) the exclusion from the whole organic food chain of animal cloning, of rearing artificially induced polyploid animals and of ionising radiation;

(j) the observance of a high level of animal welfare respecting species-specific needs.

Second, point 1.3.2.2 of Part III of Annex II to Regulation (EU) No 2018/848 provides as follows:

"3.1.2.2. With regard to breeding, the following rules shall apply:

(a) hormones and hormone-derivates shall not be used;

(b) the artificial production of monosex strains, except by hand-sorting, the induction of polyploidy, artificial hybridisation and cloning shall not be used;

(c) appropriate strains shall be chosen."

Third, point 3.1.6.2 of Part III of Annex II to Regulation (EU) No 2018/848 concerning animal welfare reads as follows:

"The handling of aquaculture animals shall be minimised, and shall be undertaken with the greatest care. Proper equipment and protocols shall be used to avoid stress and physical damage associated with handling procedures. Broodstock shall be handled in such a manner as to minimise physical damage and stress, and shall be handled under anaesthesia where appropriate. Grading operations shall be kept to a minimum and shall only be used where required to ensure fish welfare."

4.5. FOOD

1) Can certain non-organic ingredients such as steviol-glycosides and medium chain triglycerides (MCT) oil be used in the production of organic chocolate?

No. According to Article 30 of Regulation (EU) 2018/848, in order to apply the term organic in the sales description of a processed food as chocolate, at least 95% of the ingredients of agricultural origin must be organically produced. Thus, only a maximum of 5% of the agricultural ingredients can be non-organic. Moreover, the processed food has to comply with the rules on the production of organic processed food as laid down in Article 16 of Regulation (EU) 2018/848.

In addition, non-organic ingredients can only be added when they are authorised in accordance with Article 25 of Regulation (EU) 2018/848 and it implies a procedure of authorisation from the Member State and the Commission. Consequently, the list of non-organic ingredients that have been authorised and can currently be used in the EU is included in Commission Implementing Regulation (EU) 2021/1165.

In addition, Member States can give provisional authorisations for additional non-organic ingredients to be used under certain restricted conditions as set out in Article 25 of Regulation (EU) 2018/848.

Steviol-glycosides which derive from plant extract are not listed in any of the annexes to Regulation (EU) 2018/848. MCT oil is also not mentioned in itself in any of the annexes of that regulation.

Moreover, MCT oil can have several origins and methods of production and, depending on its origin and production method, it can, for example, qualify as an authorised non-organic ingredient falling under *"Fats and oils whether or not refined, but not chemically modified, derived from plants other than cacao, coconut, olive safflower, palm, rape, sesame or soya"*.

Therefore, using Steviol-glycosides and MCT Oil as additive or processing aids in organic products is currently not authorised and thus it is not possible to obtain organic certification for products containing them.

2) Can potassium sorbate be used in enzymes for the organic production of chocolate stuffing?

No. Regulation (EU) 2018/848 establishes the rules on organic production and labelling of organic products. All organic production products using terms referring to organic production must adhere to this legislation.

Article 6 of Commission Implementing Regulation (EU) 2021/1165 provides that: *"For the purposes of point (a) of Article 24(2) of Regulation (EU) 2018/848, only the products and substances listed in Part A of Annex V to this Regulation may be used as food additives, including food enzymes to be used as food additives, and processing aids in the production of processed organic food, provided that their use is in accordance with the relevant provisions of Union law, in particular Regulation*

(EC) No 1333/2008 of the European Parliament and of the Council(15)and, where applicable, in accordance with national provisions based on Union law."

Potassium sorbate is neither authorised in Section A1 of Annex V to Commission Implementing Regulation (EU) 2021/1165 (food additives including carriers) nor in its Section A2 (*processing aids and other products, which may be used for processing of ingredients of agricultural origin from organic production*). Consequently, an enzymatic preparation containing potassium sorbate cannot be used in the production of organic processed food.

3) Is the use of sulphites allowed in the production of organic grape juice for direct consumption?

No. Regulation (EU) 2018/848 applies without prejudice to other Union provisions or national provisions, in conformity with Union law, such as provisions governing the production, preparation, marketing, labelling and control, including legislation on foodstuffs and animal nutrition.

Regulation (EC) No 1333/2008 on food additives does not allow the use of sulphites (E220 – E 228) in grape juice except for unfermented grape juice for sacramental use and concentrated grape juice for home wine-making, as per point 14.1.2 of Part E of Annex II to that Regulation.

As a result, the use of sulphites (E220 – E 228) cannot be allowed in the organic production of grape juice for a direct consumption.

4) Is the heating of frozen fully baked bread a 'preparation' or 'processing' according to Regulation (EU) 2018/848?

Pursuant to Article 3(44) of Regulation (EU) 2018/848, *"preparation" means the operations of preserving or processing of organic or in-conversion products, or any other operation that is carried out on an unprocessed product without altering the initial product, such as slaughtering, cutting, cleaning or milling, as well as packaging, labelling or alterations made to the labelling relating to organic production;"*

Pursuant to Article 2(1)(m) of Regulation (EC) No 852/2004, *'processing" means any action that substantially alters the initial product, including heating, smoking, curing, maturing, drying, marinating, extraction, extrusion or a combination of those processes.*

Article 3(73) provides that *"'processing' means processing as defined in point (m) of Article 2(1) of Regulation (EC) No 852/2004; this includes the use of substances referred to in Articles 24 and 25 of this Regulation but does not include packaging or labelling operations;"*.

It follows from the above that preparation operations cover also processing actions such as heating frozen fully baked bread.

Article 34(1) of Regulation (EU) 2018/848 further provides that "prior to placing any products on the market as "organic" or as "in-conversion" or prior to the conversion

periods, operators and groups of operators referred to in Article 36 which produce, prepare, distribute [...] or which place such products on the market shall notify their activity to the competent authorities of the Member State in which it is carried out and in which their undertaking is subject to the control system.”

Therefore, a retailer heating bake-off bread has to notify its activity to the competent authorities of the Member State where its activity is carried out and submit its undertaking to the control system on organic production.

5) Can plant proteins from wheat, peas or potatoes be used for the clarification of fruit juices?

Regulation (EU) 2018/848 establishes the organic food production rules and is based on the principle of promotion of a maximum use of natural methods and inputs, which are integral to the production system; the use of external inputs is restricted and subject to authorisation (Articles 24 and 25).

On this basis, Commission Implementing Regulation (EU) 2021/1165 authorises certain products and substances for use in organic production and establishes their lists.

The use of plant proteins from wheat, peas or potatoes for clarification of fruit juices is not listed in Part A2 of Annex V of Commission Implementing Regulation (EU) 2021/1165, which in particular lists the processing aids and other products which may be used for processing of ingredients of agricultural origin from organic production.

Therefore, the use of plant proteins from wheat, peas or potatoes for clarification of fruit juices in organic production must be examined to see if it is in line with the objectives and principles of organic production. For this purpose, a request must be sent by a Member State; this request is then evaluated by the Expert Group for Technical Advice on Organic Production (EGTOP). Should EGTOP provide a positive advice on the use of the use of plant proteins from wheat, peas or potatoes for the clarification of fruit juices, the Commission can propose to the Committee on organic production to add this in Part A2 of Annex V of Commission Implementing Regulation (EU) 2021/1165.

6) Which food additive can be used in organic fresh fruit and vegetables?

Only food additives that are included in Annex II to Regulation (EC) No 1333/2008 can be placed on the market in the EU and used in foods under the conditions of use specified in Annex II. Regulation (EC) No 1333/2008 neither distinguishes between organic and conventional food production nor defines 'ecological' or "organic" food additives.

In part E of Annex II to Regulation (EC) No 1333/2008, food category 04.1 covers unprocessed fruit and vegetables; 'unprocessed food' is further defined in Article 3(2)(d) of Regulation (EC) No 1333/2008. Only the additives mentioned in that food

category and/or subcategories can be used in foods under the conditions of use specified in the Annex (columns 4 to 6).

In addition, according to point 2.2.1. of Part IV of Annex II to Regulation (EU) 2018/848, which concerns processed food, only food additives authorised pursuant to Article 24 of that regulation can be used in organic food production. In particular, only substances listed in Section A1 of Part A of Annex V of Commission Implementing Regulation (EU) 2021/1165 can be used as additives in some organic foodstuffs, under the specific conditions and limits set out in the Section A1 (columns 3 and 4).

In its Article 3, point (73), Regulation (EU) 2018/848 refers to Article 2(1), point (m) of Regulation (EC) No 852/2004 for the definition of processing and expands this definition to include in particular *"the use of substances referred to in Article 24 of this Regulation"*. Consequently, the use of food additives in unprocessed organic fruit and vegetables would turn them into processed products. When specifically authorised under the Regulation (EC) No 1333/2008 and under Regulation (EU) 2021/1165, food additives can therefore also be used in organic fruit and vegetables.

For more targeted information on organic production, please contact the competent authority of your Member State. A list of the EU competent authorities in each Member State is available at:

https://agriculture.ec.europa.eu/farming/organic-farming/organic-production-and-products/organsics-references_en

7) Can steviol glycosides (E960) be used as food additive in organic production?

Regulation (EU) 2018/848 establishes the rules on organic production and labelling of organic products. All organic production products using terms referring to organic production must adhere to this legislation.

Article 6 of Commission Implementing Regulation (EU) 2021/1165 provides that: *"For the purposes of point (a) of Article 24(2) of Regulation (EU) 2018/848, only the products and substances listed in Part A of Annex V to this Regulation may be used as food additives, including food enzymes to be used as food additives, and processing aids in the production of processed organic food, provided that their use is in accordance with the relevant provisions of Union law, in particular Regulation (EC) No 1333/2008 of the European Parliament and of the Council(15) and, where applicable, in accordance with national provisions based on Union law."*

Steviol glycosides are not authorised in Section A1 of Annex V to Commission Implementing Regulation (EU) 2021/1165 (food additives including carriers). Consequently, they cannot be used as food additive in organic products.

In 2012, pursuant to Article 21 of Regulation (EC) No 834/2007, certain Member States requested the inclusion of steviol glycosides in that Annex VIII and such request was published on the following website:

https://agriculture.ec.europa.eu/document/download/e3894487-2687-4e7a-8755-3934e8690f24_en?filename=requests-annex-viii-ix_en.pdf

It was evaluated by the independent Expert Group for Technical advice on Organic Production (EGTOP). A report which includes the evaluation of steviol glycosides was published on the following website:

https://agriculture.ec.europa.eu/document/download/3f4a3356-1815-4179-b22b-d54308801fc6_en?filename=final_report_egtop_on_organic_food_en.pdf

EGTOP found steviol glycosides not to be in line with the principles of the organic legislation. This decision was shared with the Committee on organic production.

8) Can chemical substances be used in steam processing of foods such as oat flakes?

Article 2(4) of Regulation (EU) 2018/848 provides that *"Except where otherwise provided, this Regulation applies without prejudice to related Union legislation, in particular, legislation in the fields of safety of the food chain, animal health and welfare, plant health and plant reproductive material."* Thus, the maintenance of steam processing equipment for the production of food has to comply with requirements of, among others, with the food hygiene Regulation (EC) No 853/2004, the food contact material Regulation (EC) No 1935/2004 and the Contaminants Regulation (EC) No 315/1993.

Please note in particular point 5 of Chapter VII of Regulation (EC) No 853/2004 relating to water supply, which provides that *"steam used directly in contact with food is not to contain any substance that presents a hazard to health or is likely to contaminate the food"*.

Please also note that point 3 of Chapter V of Regulation (EC) No 853/2004 on equipment requirements provides that *"where chemical additives have to be used to prevent corrosion of equipment and containers, they are to be used in accordance with good practice."*

9) Can food supplements produced only from vitamins and minerals be labelled as organic? Can non-organic vitamins be added to a multivitamin food supplement labelled as organic?

No.

Article 2(1) of Regulation (EU) 2018/848 provides that *"This Regulation applies to the following products originating from agriculture, including aquaculture and beekeeping, as listed in Annex I to the TFEU and to products originating from those products, where such products are, or are intended to be, produced, prepared, labelled, distributed, placed on the market, imported into or exported from the Union: (a) live or unprocessed agricultural products, including seeds and other plant reproductive material; (b) processed agricultural products for use as food; (c) feed (...)"*

Consequently, only food supplements produced from agricultural ingredients fall under the scope of Regulation (EU) 2018/848 and can be labelled as organic. By contrast, food supplements produced only from vitamins and minerals do not fall under the scope of organic legislation and cannot be labelled as organic.

10) Could shilajit powder be authorised under Article 25 of Regulation (EU) 2018/848 as non organic agricultural ingredient to be used in organic production?

No.

Shilajit is a natural exudation of variable consistency from layers of rocks mainly found in the Himalayas and consisting of a complex mixture of organic humid substances and plant and microbial metabolites, traditionally used in Ayurvedic medicine.

Shilajit powder cannot be considered as an agricultural ingredient as it is not covered by any category of the agricultural products listed in Annex I to the Treaty on the Functioning of the European Union. This product is also not listed in Annex I of Regulation (EU) 2018/848. It cannot therefore be the subject of an authorisation under Article 25 of Regulation (EU) 2018/848, which relates to the authorisation of non-organic agricultural ingredients for processed organic food by Member States.

11) Could enzymes be used in organic food?

Yes.

First, the specific principles applicable to the processing of organic food are laid down in Article 7 of Regulation (EU) 2018/848, which states that: "*(b) the restriction of the use of food additives, of non-organic ingredients with mainly technological and sensory functions, and of micronutrients and processing aids, so that they are used to a minimum extent and only in cases of essential technological need or for particular nutritional purposes;*".

Second, Article 24(2) of the same Regulation provides as follows: "*...the Commission may authorise certain products and substances for use in the production of processed organic food and of yeast used as food or feed, and shall include any such authorised products and substances in restrictive lists, for the following purposes:*

(a) as food additives and processing aids; (...)"

Third, Article 9(3) of Regulation (EU) 2018/848 requires an authorisation for the use of processing aids and food additives in organic production: *"For the purposes and uses referred to in Articles 24 and 25 and in Annex II, only products and substances that have been authorised pursuant to those provisions may be used in organic production, provided that their use in non-organic production has also been authorised in accordance with the relevant provisions of Union law and, where applicable, in accordance with national provisions based on Union law"*.

Fourth, point 2.2.2. of Part IV of Annex II to Regulation (EU) 2018/848 authorises the use of food enzymes in organic processed food *"provided that food enzymes to be used as food additives have been authorised pursuant to Article 24 for use in organic production"*.

Consequently, when an enzyme is used as a processing aid that is normally used in food processing, the food enzyme preparation to be used as a processing aid can be used in organic production, when it is not produced from or by Genetically Modified Organisms (see Article 11 of Regulation (EU) 2018/848).

N.B: For the categorisation of food enzymes, please also consider the DG SANTE Guidance available here: [*fs_food-improvement-agents_enzymes-guidance-categorisation.pdf](https://ec.europa.eu/food/fs/food-improvement-agents_enzymes-guidance-categorisation.pdf) (europa.eu)

12) Can *Lithothamnium calcareum* be used in all organic processed food?

No.

Point 2.2.2(f) of Part IV of Annex II to Regulation (EU) 2018/848 is relevant and provides as follows:

"(f) minerals (trace elements included), vitamins, amino acids and micronutrients, provided that:

- (i) their use in food for normal consumption is 'directly legally required', in the meaning of being directly required by provisions of Union law or provisions of national law compatible with Union law, with the consequence that the food cannot be placed at all on the market as food for normal consumption if those minerals, vitamins, amino acids or micronutrients are not added; or*
- (ii) as regards food placed on the market as having particular characteristics or effects in relation to health or nutrition or in relation to needs of specific groups of consumers:*

— in products referred to in points (a) and (b) of Article 1(1) of Regulation (EU) No 609/2013 of the European Parliament and of the Council their use is authorised by that Regulation and acts adopted on the basis of Article 11(1) of that Regulation for the products concerned, or— in products regulated by Commission Directive 2006/125/EC , their use is authorised by that Directive".

The main component of *Lithothamnium calcareum* is calcium carbonate and its main function in processed food corresponds to the addition of calcium.

Consequently, given that calcium carbonate is a mineral, its use in organic production requires an authorisation pursuant to point 2.2.2 of Part IV of Annex II to Regulation (EU) 2018/848.

13) Can organic pulp and cells be added to organic juice produced from concentrate?

Yes, under certain conditions and if these pulp and cells from fruit are produced in accordance with the organic production rules.

First, and in accordance with point 1(b) of Part 1 of Annex I to Council Directive 2001/112/EC, pulp and cells from fruit from the same species of fruit may be added to conventional juice during its production.

Second, Article 16(1) of Regulation (EU) 2018/848 provides that *'operators that produce processed food shall comply, in particular, with the detailed production rules set out in Part IV of Annex II'*. Third, pursuant to point 2.2.1. of Part IV of Annex II to Regulation (EU) 2018/848, certain non-organic agricultural ingredients when authorised pursuant to Article 24 or Article 25 of that Regulation may be used in organic production. However, pulp and cells from fruit are neither authorised according to Article 24 or Article 25, nor are they listed in the specific authorised products and substances to be used in the processing of food in point 2.2.2. of Part IV of Annex II to Regulation (EU) 2018/848.

Only organic pulp and cells from fruit can therefore be added to organic juice produced from concentrate.

14) Do essential oils need to be organic when used as flavourings in the processing of organic food?

No, provided that certain conditions are met.

The authorisation for using flavourings in organic food is provided by point 2.2.2 (b) of Part IV of Annex II to Regulation (EU) 2018/848, which reads as follows:

'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.'

The provision does not therefore require that natural flavourings have to be organic. An essential oil that is used as a flavouring and corresponds to a substance, or a product described under point 2.2.2 (b) of Part IV of Annex II to Regulation (EU) 2018/848, does not therefore need to be organic in order to be used in processed organic food.

15) Can a plant-based product enriched in vitamin D on the basis of a national rule be considered and labelled as organic?

Yes, under certain conditions, namely when, in accordance with a national rule, certain plant-based products contain a certain minimum content of vitamin D per 100 grams when placed on the relevant national market.

Point 2.2.2(f) of Part IV of Annex II to Regulation (EU) 2018/848 provides as follows: *'2.2.2. In the processing of food, the following products and substances may be used: (...) (f) minerals (trace elements included), vitamins, amino acids and micronutrients, provided that:*

- (i) their use in food for normal consumption is 'directly legally required', in the meaning of being directly required by provisions of Union law or provisions of national law compatible with Union law, with the consequence that the food cannot be placed at all on the market as food for normal consumption if those minerals, vitamins, amino acids or micronutrients are not added; or*
- (ii) as regards food placed on the market as having particular characteristics or effects in relation to health or nutrition or in relation to needs of specific groups of consumers:
— in products referred to in points (a) and (b) of Article 1(1) of Regulation (EU) No 609/2013 of the European Parliament and of the Council their use is authorised by that Regulation and acts adopted on the basis of Article 11(1) of that Regulation for the products concerned, or*

— in products regulated by Commission Directive 2006/125/EC, their use is authorised by that Directive’.

In accordance with point 2.2.2(f)(i) of Part IV of Annex II to Regulation (EU) 2018/848, a plant-based food enriched in vitamin D on the basis of a national requirement can be labelled as organic if this food is produced and labelled in accordance with Regulation (EU) 2018/848. This food can only be sold/labelled as organic in the Member State where the corresponding nutrition obligation is applicable. In Member States where no similar nutrition obligation is required, this food cannot be sold/labelled as organic as it does not respect the above-mentioned provision on the use of vitamins in organic processed food.

16) What are the flavourings that can be used in organic food processed products?

In accordance with point 2.2.2(b) of Part IV of Annex II to Regulation (EU) 2018/848, flavourings may be used in the processed organic food when they both:

- correspond to the substances and products defined in points (c) and (d)(i) of Article 3(2) of Regulation (EC) No 1334/2008; and
- are labelled, when sold to the food producers, as natural flavouring substances or as natural flavouring preparations in accordance with Article 16(2), (3) and (4) of Regulation (EC) No 1334/2008.

Flavourings that have been labelled in accordance with Article 16(2), (3) and (4) of Regulation (EC) No 1334/2008 must have the following characteristics:

- the flavouring component must comprise only flavouring preparations and/or natural flavouring substances;
- the flavouring component of the flavouring substances must contain exclusively natural flavouring substances and
- the flavouring component has to be obtained exclusively or by at least 95 % by w/w (weight concentration) from the source material that reflects the flavour of taste of the flavouring component.

17) Can casings be used in organic processed food?

Yes, under certain conditions.

In accordance with Article 24 of Regulation (EU) 2018/848, the non-organic ingredients that have been authorised for use in the production of processed organic food are listed in Part B of Annex V to Commission Implementing Regulation (EU) 2021/1165. This list contains 'casings' with the specific conditions that they originate "*from natural raw materials of animal or from plant origin material*".

Natural casings obtained in slaughterhouses, casings made from collagen derived from the skin of animals, and casings made from cellulose derived from plants, are therefore authorised to be used as non-organic agricultural ingredients in organic processed food.

The processed food containing casings may use the terms referring to organic production in its sales description if at least 95% of the agricultural ingredients of this food product by weight are organic and if all the other applicable rules are respected. In such a case, casings and the other non-organic agricultural ingredients of the food product at stake must therefore represent a maximum of 5% of the agricultural ingredients by weight of this processed food.

4.6. FEED

1) Can I use silage additives in organic feed production?

Yes but Only silage additives listed in Part B (1)(e) of Annex III to Commission Implementing Regulation 2021/1165 can be used in the processing of organic silage. They can only be used when weather conditions do not allow for adequate fermentation.

<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32021R1165&from=EN>

2) Can Ethylenediaminetetra-acetic acid (EDTA) be used as feed additive in poultry feedingstuff?

No. The feed additives that can be used in organic production, in accordance with Article 4 of Commission Implementing Regulation (EU) 2021/1165 are listed in Part B of Annex III of that Regulation. EDTA cannot be used as it is not included in that list.

3) Which minerals can be used in organic petfood containing ingredients stemming from fishing or hunting?

Feed materials of mineral origin can be used in organic pet food whose main ingredient is a product of hunting or fishing, provided that these feed materials comply with the relevant provisions of Union law, in particular Regulation (EC) No 767/2009.

Article 3(2) of Regulation (EU) 2023/2419 on the labelling of organic pet food which relates to the use of the terms referring to organic production (i.e. the terms referred to in Article 30(1) of Regulation (EU) 2018/848) in the sales description and in the list of ingredients of pet food containing ingredients that stem from hunting or fishing is relevant and states that:

'2. For pet food containing ingredients stemming from hunting or fishing, the terms referred to in Article 30(1) of Regulation (EU) 2018/848 may be used in the sales description and in the list of ingredients provided that:

(a) the main ingredient is a product of hunting or fishing;

(b) those terms are clearly related in the sales description to an organic ingredient other than the main ingredient;

(c) all other agricultural ingredients are organic;

(d) only feed additives and processing aids authorised pursuant to Article 24 of Regulation (EU) 2018/848 are used in the processing of the pet food; and

(e) the pet food complies with the detailed production rules set out in points 1.5, 2.1, 2.2 and 2.4 of Part V of Annex II to Regulation (EU) 2018/848 and with the processing techniques laid down in accordance with Article 17(3) of that Regulation.'

Feed materials of mineral origin may therefore be present in the composition of the pet food whose main ingredient is a product of hunting or fishing, provided that these feed materials comply with the relevant provisions of Union law, in particular Regulation (EC) No 767/2009.

Please note that, pursuant to point (a) of Article 3(1) of Regulation (EU) 2023/2419, for pet food **not** composed of hunting or fishing products and bearing the terms referring to organic production in its sales description and in its list of ingredients, *'only non-organic feed material of plant, algal, animal or yeast origin, feed material of mineral origin, and feed additives and processing aids authorised pursuant to Article 24 for use in organic production may be used in the processing of feed'* in accordance with point 2.3 of Part V of Annex II to Regulation (EU) 2018/848. The feed materials of mineral origin authorised for use in organic production are listed in Part A(1) of Annex III to Regulation (EU) 2021/1165.

4.7. WINE

1) Can electrodialysis treatment be used to ensure the tartaric stabilisation of wine in accordance with point 36 of Annex I A to Regulation (EC) 606/2009 for the production of organic wine?

No. The use of electrodialysis treatment to ensure the tartaric stabilisation of the wine is prohibited in organic production by point 3.2(c) of Part VI of Annex II to Regulation (EU) 2018/848:

"The use of the following oenological practices, processes and treatments shall be prohibited: (...) (c) electrodialysis treatment to ensure the tartaric stabilisation of the wine in accordance with point 36 of Annex I A to Regulation (EC) No 606/2009".

2) Can non-organic wine made up of less than 100% of organic grapes be labelled as organic?

No.

Wine is included in the scope of Regulation (EU) 2018/848 and specific detailed production rules are included in Part VI of Annex II of that Regulation. Those rules: (i) provide that organic wine must be produced from organic grapes: and (ii) set limitations as regards the use of products, substances and oenological practices.

In accordance with Article 30 of Regulation (EU) 2018/848, the use of terms referring to organic production is restricted to products complying with this Regulation. *'Furthermore, no terms including terms used in trademarks or company names or practices shall be used in labelling or advertising if they are liable to mislead the consumer or user by suggesting that a product or its ingredients comply with this Regulation'* (see Article 30(2) of Regulation (EU) 2018/848).

Wine that does not comply with the detailed organic production rules of Regulation (EU) 2018/848 cannot therefore use terms referring to organic production.

Furthermore, in accordance with Article 30(5), point (a), of Regulation (EU) 2018/848, the use of terms referring to organic production is excluded in the sales description for a product when less than 95% of the product's agricultural ingredients by weight is organic.

Article 30(5), point (b), of Regulation (EU) 2018/848 provides for the possibility to use terms referring to organic production only in the list of ingredients of an organic product when less than 95 % of the agricultural ingredients of the product by weight are organic and provided that certain conditions are respected.

Generic mentions such as “wine from organic grapes” and “product containing less than 95 % organic ingredients” cannot therefore be used in the sales description of non-organic wine made with organic grapes. There is no possibility to refer to organic production in the label of such a wine and the label should correspond to that of a conventional wine.

4.8 YEAST

1) Which organic production requirements apply to the production of organic salt?

Sea salt and other salts for food and feed are listed in Annex I to Regulation (EU) 2018/848²⁵ and Regulation (EU) 2018/848 therefore applies to these products, when they are, or are intended to be, produced, prepared, labelled, distributed, placed on the market, imported into or exported from the Union.

In accordance with Article 21(2) of Regulation (EU) 2018/848, in the absence of detailed production rules, operators producing salts, *"shall (...) comply with the relevant principles laid down in Articles 5 and 6, mutatis mutandis with the principles laid down in Article 7, and with the general production rules laid down in Articles 9 to 11" (...) a Member State may, as regards products referred to in paragraph 1, apply detailed national production rules, provided that those rules are in accordance with this Regulation, and provided that those rules are in accordance with this Regulation, and provided that they do not prohibit, restrict or impede the placing on the market of products which have been produced outside its territory and which comply with this Regulation"*.

2) Can organic private standards be applied for certification of organic salts?

Yes, under certain conditions.

Operators producing sea salt and other salts for food and feed listed in Annex I to Regulation (EU) 2018/848 can be certified under a national organic control system within the meaning of Article 34 of Regulation (EU) 2018/848.

In the current absence of a delegated act providing detailed production rules for these organic salts, two situations should be distinguished on the basis of Article 21(2) of Regulation (EU) 2018/848:

1) if there are no detailed production rules adopted at national level:

"operators shall, as regards products referred to in paragraph 1, comply with the principles laid down in Articles 5 and 6, mutatis mutandis with the principles laid

²⁵ In box 6 of Part I of the certificate of the operator, sea salt and other salts for food and feed must therefore be referenced as belonging to "product category (g)" of Article 35(7) of Regulation 2018/848 (i.e. "other products listed in Annex I to Regulation 2018/848 or not covered by the previous categories listed in Article 35(7)). The certificate referred to in Article 35(1) of Regulation (EU) 2018/848 is issued by national authorities (or control authorities or control bodies), in accordance with the model set out in Annex VI to that Regulation. This document confirms that the activity of the operator complies with Regulation (EU) 2018/848.

down in Article 7, and with the general production rules laid down in Articles 9 to 11,” (point(a) of Article 21(2));

2) if there are detailed production rules at national level:

“a Member State may, as regards products referred to in paragraph 1, apply detailed national production rules, provided that those rules are in accordance with this Regulation, and provided that they do not prohibit, restrict or impede the placing on the market of products which have been produced outside its territory and which comply with this Regulation.”(point (b) of Article 21(2)).

These situations do not prevent the possibility of setting private standards for the production of organic salts. Such standards must comply with all the applicable provisions and, in principle, they can go beyond the applicable ‘organic’ requirements. In this context, please note the EU best practice guidelines for voluntary certification schemes for agricultural products and foodstuffs were published by the Commission in December 2010 (Commission Communication — EU best practice guidelines for voluntary certification schemes for agricultural products and foodstuffs, OJ C 341, 16.12.2010, p. 5).

When private standards are elaborated in third countries for the production of organic salts that are intended to be imported into the Union under the compliance import regime (Article 46 of Regulation (EU) 2018/848), these standards need to be included in the technical dossier referred to in Article 46(4) of Regulation (EU) 2018/848, which is submitted by control authorities and control bodies for recognition by the Commission in accordance with Article 46. In this specific case, the control authority and/or the control body that wants to certify organic salts needs to include in its technical dossier a request to be recognised for organic salts²⁶.

²⁶ Organic salts must be referenced as belonging to “product category (g)” of Article 35(7) of Regulation 2018/848 (i.e. “other products listed in Annex I to Regulation 2018/848 or not covered by the previous categories listed in Article 35(7)).

5. TRANSITIONAL MEASURES

1) Can products bearing a reference indicating that they can be used in organic farming in accordance with Regulation (EC) No 834/2007 continue to be placed on the market after 1 January 2022?

Article 60 of Regulation (EU) 2018/848 provides that products produced in accordance with Regulation (EC) 834/2007 before 1 January 2022 may be placed on the market after that date until stocks are exhausted. This provision applies to stocks of products falling within the scope of the EU organic legislation, such as food and feed certified according to Regulation (EC) 834/2007. Plant protection products, fertilisers and soil conditioners bearing the indication that they can be used as organic inputs do not fall within the scope of the EU organic legislation.

Nevertheless, the EU organic legislation does not prevent the marketing of these products with a reference to Regulation (EC) 834/2007 after 1 January 2022. Thus, plant protection products, fertilisers or soil conditioners with an indication *"this product may be used in organic agriculture according to Council Regulation (EC) No 834/2007"* may continue to be placed on the market after 1 January 2022 until stocks are exhausted as long as the products or substances therein continue to be authorised under Regulation (EU) 2018/848.

6. APPENDIX LEGISLATION REFERENCES

- 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*) ELI: <http://data.europa.eu/eli/reg/2018/848/oj>
- Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91 (*OJ L 189, 20.07.2007, p.1*) ELI: <http://data.europa.eu/eli/reg/2007/834/oj>
- Commission Regulation (EC) No 889/2008 of 5 September 2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control (*OJ L 250, 18.9.2008, p.1*) ELI: <http://data.europa.eu/eli/reg/2008/889/2022-01-01>
- Commission Implementing Regulation (EU) 2020/464 of 26 March 2020 laying down certain rules for the application of Regulation (EU) 2018/848 of the European Parliament and of the Council as regards the documents needed for the retroactive recognition of periods for the purpose of conversion, the production of organic products and information to be provided by Member States (*OJ L 98, 31.3.2020, p.2*) ELI: http://data.europa.eu/eli/reg_impl/2020/464/oj
- Commission Implementing Regulation (EU) 2021/1165 of 15 July 2021 authorising certain products and substances for use in organic production and establishing their lists (*OJ L 253, 16.7.2021, p.13*) ELI: http://data.europa.eu/eli/reg_impl/2021/1165/oj
- Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 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 (*OJ L 031, 1.2.2002, p.1*) ELI: <http://data.europa.eu/eli/reg/2002/178/2024-07-01>
- Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive

2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (*OJ L 304 22.11.2011, p 18*) ELI: <http://data.europa.eu/eli/reg/2011/1169/oj>

- Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, (*OJ L 309 24.11.2009, p. 1*) ELI: <http://data.europa.eu/eli/reg/2009/1107/oj>
- Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (*OJ L 153, 11.6.2011, p. 1*) ELI: http://data.europa.eu/eli/reg_impl/2011/540/oj
- Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (*OJ L 181, 29.6.2013, p.35*) ELI: <http://data.europa.eu/eli/reg/2013/609/oj>
- Commission Directive 2006/125/EC of 5 December 2006 on processed cereal-based foods and baby foods for infants and young children (*OJ L 339, 6.12.2006, p.16*) ELI: <http://data.europa.eu/eli/dir/2006/125/oj>
- Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms (*OJ L 106, 17.4.2001, p.1*) ELI: <http://data.europa.eu/eli/dir/2001/18/oj>
- Regulation (EC) N° 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, Article 12(2) (*OJ L 268, 18.10.2003, p. 1*) ELI: <http://data.europa.eu/eli/reg/2003/1829/oj>
- Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (*OJ L 268, 18.10.2003, p. 24*) ELI: <http://data.europa.eu/eli/reg/2003/1830/oj>

- Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC (*OJ L 127, 29.4.2014 p.1*) ELI: <http://data.europa.eu/eli/dir/2014/40/oj>
- Commission Regulation (EU) 2017/893 of 24 May 2017 amending Annexes I and IV to Regulation (EC) No 999/2001 of the European Parliament and of the Council and Annexes X, XIV and XV to Commission Regulation (EU) No 142/2011 as regards the provisions on processed animal protein (*OJ L 138, 25.5.2017, p.1*) ELI: <http://data.europa.eu/eli/reg/2017/893/oj>
- Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption (*OJ L 330, 5.12.1998, p. 32*) ELI: <http://data.europa.eu/eli/dir/1998/83/oj>
- Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (*OJ L 327, 11.12.2015, p. 1*) ELI: <http://data.europa.eu/eli/reg/2015/2283/oj>
- Regulation (EC) 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (*OJ L 139, 30.04.2004,p.1*) ELI: <http://data.europa.eu/eli/reg/2004/852/2021-03-24>
- Regulation (EC) 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (*OJ L 338, 27.10.2004, p. 4*) ELI: <http://data.europa.eu/eli/reg/2004/1935/oj>
- Council Regulation No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food (*OJ L 37, 13.02.1993, p. 1*) ELI: <http://data.europa.eu/eli/reg/1993/315/oj>
- Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom (*OJ L 13, 17/01/2014, p. 1*) ELI: <http://data.europa.eu/eli/dir/2013/59/oj>

- Commission Implementing Regulation (EU) 2019/2072 of 28 November 2019 establishing uniform conditions for the implementation of Regulation (EU) 2016/2031 of the European Parliament and the Council, as regards protective measures against pests of plants, and repealing Commission Regulation (EC) No 690/2008 and amending Commission Implementing Regulation (EU) 2018/2019 (OJ L 319, 10.12.2019, p.1) ELI: http://data.europa.eu/eli/reg_impl/2019/2072/oj
- Commission Regulation (EU) 2021/1372 of 17 August 2021 amending Annex IV to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards the prohibition to feed non-ruminant farmed animals, other than fur animals, with protein derived from animals (OJ L 295, 18.8.2021, p.1) ELI: <http://data.europa.eu/eli/reg/2021/1372/oj>
- Regulation (EU) 2019/787 of the European Parliament and of the Council of 17 April 2019 on the definition, description, presentation and labelling of spirit drinks, the use of the names of spirit drinks in the presentation and labelling of other foodstuffs, the protection of geographical indications for spirit drinks, the use of ethyl alcohol and distillates of agricultural origin in alcoholic beverages, and repealing Regulation (EC) No 110/2008 (OJ L 130, 17.5.2019, p. 1) ELI: <http://data.europa.eu/eli/reg/2019/787/oj>
- Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p.59) ELI: <http://data.europa.eu/eli/reg/2009/1223/oj>
- Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1) ELI: <http://data.europa.eu/eli/reg/2005/396/oj>
- Commission Regulation (EC) No 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food (OJ L 384, 29.12.2006, p. 75) ELI: <http://data.europa.eu/eli/reg/2006/2023/oj>
- Commission Implementing Regulation (EU) 2021/279 of 22 February 2021 laying down detailed rules for the implementation of Regulation (EU) 2018/848 of the European Parliament and of the Council on controls and other measures ensuring traceability and compliance in organic production and the labelling of organic products (OJ L 62, 23.2.2021, p. 6) ELI: http://data.europa.eu/eli/reg_impl/2021/279/oj

- Commission Implementing Regulation (EU) No 798/2013 of 21 August 2013 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance pyrethrins (OJ L 224, 22.8.2013, p. 9) ELI:http://data.europa.eu/eli/reg_impl/2013/798/oj

- Regulation (EU) 2016/2031 of the European Parliament of the Council of 26 October 2016 on protective measures against pests of plants, amending Regulations (EU) No 228/2013, (EU) No 652/2014 and (EU) No 1143/2014 of the European Parliament and of the Council and repealing Council Directives 69/464/EEC, 74/647/EEC, 93/85/EEC, 98/57/EC, 2000/29/EC, 2006/91/EC and 2007/33/EC (OJ L 317, 23.11.2016, p. 4) ELI:<http://data.europa.eu/eli/reg/2016/2031/oj>

- Commission Delegated Regulation (EU) 2021/1189 of 7 May 2021 supplementing Regulation (EU) 2018/848 of the European Parliament and of the Council as regards the production and marketing of plant reproductive material of organic heterogeneous material of particular genera or species (OJ L 258, 20/07/2021, p. 18) ELI :http://data.europa.eu/eli/reg_del/2021/1189/2022-07-05

- Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights (OJ L 227, 1.9.1994, p. 1) ELI:<http://data.europa.eu/eli/reg/1994/2100/oj>

- Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (OJ L 147, 31.5.2001, p. 1) ELI:<http://data.europa.eu/eli/reg/2001/999/oj>

- Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene (OJ L 35, 8.2.2005, p. 1) ELI:<http://data.europa.eu/eli/reg/2005/183/oj>

- Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed, amending European Parliament and Council Regulation (EC) No 1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC (OJ L 229, 1.9.2009, p. 1) ELI: <http://data.europa.eu/eli/reg/2009/767/oj>

- Commission Regulation (EU) No 68/2013 of 16 January 2013 on the Catalogue of feed materials (OJ L 29, 30.1.2013, p. 1) ELI: <http://data.europa.eu/eli/reg/2013/68/oj>

- Council Directive 91/676/EEC of 12 December 1991 concerning the protection of waters against pollution caused by nitrates from agricultural sources (*OJ L 375, 31.12.1991, p. 1*) *ELI:*<http://data.europa.eu/eli/dir/1991/676/oj>
- Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (*OJ L 327, 22.12.2000, p. 1*) *ELI:*<http://data.europa.eu/eli/dir/2000/60/oj>
- Directive 2008/56/EC of the European Parliament and of the Council of 17 June 2008 establishing a framework for community action in the field of marine environmental policy (Marine Strategy Framework Directive) (*OJ L 164, 25.6.2008, p. 19*) *ELI:*<http://data.europa.eu/eli/dir/2008/56/oj>
- Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation)(*OJ L 95, 7.4.2017, p. 1*) *ELI:* <http://data.europa.eu/eli/reg/2017/625/oj>
- Commission Implementing Regulation (EU) 2019/627 of 15 March 2019 laying down uniform practical arrangements for the performance of official controls on products of animal origin intended for human consumption in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council and amending Commission Regulation (EC) No 2074/2005 as regards official controls (*OJ L 131, 17.5.2019, p. 51*) *ELI:* http://data.europa.eu/eli/reg_impl/2019/627/oj
- Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (*OJ L 354, 31.12.2008, p. 16*) *ELI:* <http://data.europa.eu/eli/reg/2008/1333/oj>
- Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No

1037/2001 and (EC) No 1234/2007 (OJ L 347, 20.12.2013, p. 671)
ELI: <http://data.europa.eu/eli/reg/2013/1308/oj>

- Regulation Regulation (EU) 2023/2419 of the European Parliament and of the Council of 18 October 2023 on the labelling of organic pet food (OJ L, 2023/2419, 27.10.2023)
ELI: <http://data.europa.eu/eli/reg/2023/2419/oj>
- Council Directive 2001/112/EC of 20 December 2001 relating to fruit juices and certain similar products intended for human consumption (OJ L 010 12.1.2002, p. 58) ELI: <http://data.europa.eu/eli/dir/2001/112/2014-10-05>