

Guidance on the obligation of origin labelling with regard to “primary ingredients of different origin” for food supplements

**In accordance with Article 26 para. 3 of Regulation (EU)
1169/2011 and Implementing Regulation (EU) 2018/775**

December 2020

The legal provisions governing country of origin labelling (COOL) are included in the Food Information to Consumers Regulation (EU) No 1169/2011 (The FIC Regulation).

COOL, which is the indication of the country of origin or place of provenance of a food, is mandatory where failure to indicate this might mislead the consumer.

In case COOL is voluntarily provided, specific requirements exist to ensure that consumers are not misled. This is particularly the case where the 'Country of origin' or the 'Place of provenance' is not the same as that of its primary ingredient. The practical requirements to deal with such cases are included in Implementing Regulation (EU) 2018/775. Some aspects are further clarified in a Commission Notice (2020/C 32/01).

This guidance document covers the application of this legislation in relation to food supplements. Additional guidance is necessary because the COOL requirement has not been included in EU food labelling legislation with food supplements in mind. Instead, it is mainly intended to cover information about the origin of major commodities of agricultural origin, used in the manufacturing of foods, such as wheat, olive oil, milk, fruit, meat, etc. For food supplements this is mostly irrelevant given that these products are taken because of their health benefits, not because of the origin of these commodities. In addition food supplements have a limited weight and are recommended to be taken in small quantities per daily consumption.

The relevance for the consumers must therefore be taken into account, otherwise the provision of COOL might not be relevant and could in certain cases in itself be misleading.

The legal provisions are summarised in the Annex to these guidelines.

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The relevance of the provisions for food supplements

Introduction

Article 26(3) of the FIC Regulation has most certainly not been designed and agreed with food supplements in mind. The intention was to address the desire of consumers to know the origin of a number of ingredients from agricultural origin and to avoid that consumers are misled in case the origin of the product is different from the origin of the primary ingredient of the product.

Article 26(4) also indicates that the focus of origin labelling is mainly on ingredients from agricultural origin:

- (a) types of meat other than beef and those referred to in point (b) of paragraph 2;
- (b) milk;
- (c) milk used as an ingredient in dairy products;
- (d) unprocessed foods;
- (e) single ingredient products;
- (f) ingredients that represent more than 50% of a food.

It is obvious that consumers regard food supplements differently from other foods when it comes to purchasing decisions. The guiding criterion for food supplements is obviously the type of vitamins, minerals and other substances and their amounts, as these are relevant for the health benefit, not their origin. For regular foods the origin may be more relevant because of quality, tradition or environmental reasons.

Nevertheless, food business operators may well be interested to indicate 'made in ..' or 'product of ...', because consumers may have an interest to know the country of origin. In such cases the ingredients used may not all come from that country.

This would be a situation that needs to be addressed in the light of the application of COOL legislation. It must in particular be addressed whether or not the difference in origin of those ingredients has to be indicated according to the relevant provisions of the FIC Regulation and the Implementing Regulation on the origin indication of primary ingredients.

Two questions to be addressed

1. Is the 'country of origin' or the 'place of provenance' of the food supplement given?

In the case of Food Supplements, the provision of COOL is **voluntary**.

In most cases, companies indicate the origin of the product with statements such as 'made in', 'produced in', 'product of' followed by the geographical indication or by means of a flag or representation indicating a country or geographic region.

This is considered COOL. The Commission Notice confirms under point 2.4.1 that statements such as 'made in (country)', 'manufactured in (country)', 'produced in (country)', are associated by consumers with an origin indication within the meaning of Article 26(3) and therefore, in principle, should be seen as indicating the 'Country of origin' or 'Place of provenance' of a food.

The Commission Notice also notes that the term 'product of' is likely to suggest to the consumer that the entire food, including its ingredients, is coming from the country indicated on the label.

Many other statements are however not to be considered as COOL. Examples include:

- Statements relating to the company, e.g.
 - "Market leader in country x"
- Statements relating to the product, e.g.
 - "No. 1 product in country XY"
 - "Product developed in country X", "Food supplement researched in country x"?

In all cases, the likely perception of the consumer should be considered to judge that such statement, in the context of the whole product presentation, would not lead to people mistakenly considering this as an indication of origin of the product.

It is also important to know that the mandatory indication of 'the name or business name and address of the food business operator' referred to in Article 8(1) according to Article 9.h of the FIC regulation is not an origin indication, not even if this would be highlighted or portrayed in bold. Such indication must mention the country of residence of the responsible food business operator.

Where no COOL is given, there is no obligation to indicate the "divergent/different" origin of a primary ingredient.

2. Does the food supplement have one or more primary ingredient(s)?

This question must be answered on the basis of the definition of **'primary ingredient'** in Article 2.q of the FIC Regulation, which has two elements: a primary ingredient is an ingredient that either:

- (a) represent **more than 50% of the food** or
- (b) which is **usually associated with the name of the food** by the consumer and for which **in most cases a quantitative indication is required**

In addition, the Commission Notice specifies that when providing information about the primary ingredient(s) of a food, food business operators should take into account various elements. In particular, in addition to the quantitative composition of the food, they have to carefully consider its specific characteristics, nature and the entire presentation of the label.

They also need to consider the consumers' perception and expectations with regard to the information provided about the food in question.

Food business operators should take into consideration whether the origin indication of a particular ingredient is likely to substantially affect consumers' purchasing decisions and whether the absence of such an origin indication would mislead consumers.

(a) Ingredients that represent more than 50% of the food supplement

In case one ingredient represents more than 50% of the food, this could trigger COOL in case the origin of that ingredient is different from that indicated for the product.

However, in the case of food supplements, because of their specific format (e.g. tablets and capsules), additives and ingredients required to manufacture the food supplement form may comprise more than 50% of the product. Examples are e.g.:

- Gelatin or HMPC used to produce the capsule
- Maltodextrin, starch, polyols or lactose to provide bulk to the product

These substances can represent more than 50% of the weight of the food supplement because of the relatively small size of sachets, tablets and capsules. It is obvious that consumers do not buy supplements for the capsule or "bulking agents" and that therefore the provision of origin information on those is not likely to govern their purchase behaviour. It may even mislead or confuse consumers as to the real origin of the product.

Therefore, the indication of the origin of an ingredient that comprises more than 50% of the food supplement should not apply to substances that are technologically required but should be reserved for ingredients that characterise the product. Examples are:

- Fish oil
- Herbs

(b) Ingredients which are usually associated with the name of the food by the consumer and for which in most cases a quantitative indication is required

In accordance with Article 17(1) of the FIC Regulation, the name of the product must be its legal name, where such exists.

The legal name of Food Supplements is "Food Supplement", as is specified in Article 6 of Directive 2002/46/EC. Although it is also a legal requirement that the names of the categories of nutrients or substances that characterise the product or an indication of the nature of those nutrients or substances must appear on the label, this is not part of the legal name.

Food supplement can therefore contain many different ingredients, which must be mentioned on the label, specified in the list of ingredients and the quantity of these must be indicated in the nutrition labelling. There is however no ingredient that consumers usually associate with the legal name "food supplement".

There is therefore legally no obligation to indicate in all cases the origin of the nutrients or other substances present in the food supplement.

In many cases, the origin of the nutrients or other substances present in the product is also not a factor that will be relevant for the purchasing decision of the consumer. Since many food supplements contain a mixture of many nutrients and other substances, the indication of the origin of each of them would result in confusing labelling. As an example:

- a multivitamin-mineral preparation can contain up to more than 25 nutrients. Since there is no nutrient that comprises more than 50% of the product, there is no primary ingredient and no further COOL is required.
- a multivitamin-mineral preparation can contain more than 50% of calcium carbonate and a little amount of vitamin D, however Vitamin D will contribute more than calcium carbonate to the daily recommended amount (Nutrient Reference Value) of these nutrients. Providing COOL of the calcium carbonate is meaningless and may even confuse consumers.

This does however not prevent companies to present further information about the origin or source of certain ingredients. As an example:

- A botanical food supplement based on a certain plant preparation could still indicate that the plant used originated from a certain geographic location, where the food business operator would want to provide such information to the consumer.

Modalities for the indication of the country of origin or place of provenance

Where a food business operator has established that the criteria for providing COOL of the primary ingredient are met, the following modalities apply:

- The information must appear in the same field of vision as the indication of the country of origin or place of provenance of the food.
- The information must be in a font size which has an x-height of at least 75% of the x-height of the indication of the country of origin or place of provenance of the food. The font size must however not be smaller than the minimum font size as required in accordance with Article 13(2) of the FIC Regulation.
- If the country of origin or place of provenance of a food is given by means of non-scriptural form, the information provided must appear in the same field of vision as the indication of the country of origin or place of provenance of the food.
- The following possibilities can be used to indicate the divergent/different origin of the primary ingredient:
 - 'EU', 'non-EU' or 'EU and non-EU'; or
 - Region, or any other geographical area either within several Member States or within third countries, if defined as such under public international law or well understood by normally informed average consumers; or
 - FAO Fishing area, or sea or freshwater body if defined as such under international law or well understood by normally informed average consumers; or
 - Member State(s) or third country(ies); or
 - Region, or any other geographical area within a Member State or within a third country, which is well understood by normally informed average consumers; or
 - The country of origin or place of provenance in accordance with specific Union provisions applicable for the primary ingredient(s) as such; or
 - by means of a statement as follows: '(name of the primary ingredient) do/does not originate from (the country of origin or the place of provenance of the food)' or any similar wording likely to have the same meaning for the consumer.

Annex: The legal requirements

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 (FIC)

Article 2 – Definitions

- “2 (g) **‘place of provenance’** means any place where a food is indicated to come from, and that is not the ‘country of origin’ as determined in accordance with Articles 23 to 26 of Regulation (EEC) No 2913/92 *; the name, business name or address of the food business operator on the label shall not constitute an indication of the country of origin or place of provenance of food within the meaning of this Regulation;
- (k) **‘field of vision’** means all the surfaces of a package that can be read from a single viewing point;
- (n) **‘legal name’** means the name of a food prescribed in the Union provisions applicable to it or, in the absence of such Union provisions, the name provided for in the laws, regulations and administrative provisions applicable in the Member State in which the food is sold to the final consumer or to mass caterers;
- (q) **‘primary ingredient’** means an ingredient or ingredients of a food that represent more than 50% of that food or which are usually associated with the name of the food by the consumer and for which in most cases a quantitative indication is required;”
3. For the purposes of this Regulation the country of origin of a food shall refer to the origin of a food as determined in accordance with Articles 23 to 26 of Regulation (EEC) No 2913/92.”

Article 26 – Country of origin or place of provenance

- “2. Indication of the country of origin or place of provenance shall be mandatory:
- (a) where failure to indicate this might mislead the consumer as to the true country of origin or place of provenance of the food, in particular if the information accompanying the food or the label as a whole would otherwise imply that the food has a different country of origin or place of provenance;
- (b) for meat falling within the Combined Nomenclature (‘CN’) codes listed in Annex XI. The application of this point shall be subject to the adoption of implementing acts referred to in paragraph 8.
3. Where the country of origin or the place of provenance of a food is given and where it is not the same as that of its primary ingredient:
- (a) the country of origin or place of provenance of the primary ingredient in question shall also be given; or
- (b) the country of origin or place of provenance of the primary ingredient shall be indicated as being different to that of the food.

The application of this paragraph shall be subject to the adoption of the implementing acts referred to in paragraph 8.”

* Reference to Regulation No 2913/92

REGULATION (EU) 952/2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code has replaced **REGULATION (EEC) 2913/92**.

Article 60 – Acquisition of origin

- “1. Goods wholly obtained in a single country or territory shall be regarded as having their origin in that country or territory.
2. Goods the production of which involves more than one country or territory shall be deemed to originate in the country or territory where they underwent their last, substantial, economically-justified processing or working, in an undertaking equipped for that purpose, resulting in the manufacture of a new product or representing an important stage of manufacture.”

For a number of goods, substantial processing or working is covered by Article 32 of Commission Delegated Regulation (EU) 2015/2446.

Commission Delegated REGULATION (EU) 2015/2446 of 28 July 2015 supplementing Regulation (EU) No 952/2013 of the European Parliament and of the Council as regards detailed rules concerning certain provisions of the Union Customs Code.

Article 32 – Goods the production of which involves more than one country or territory (Article 60(2) of the Code)

“ Goods listed in Annex 22-01 shall be considered to have undergone their last substantial processing or working, resulting in the manufacture of a new product or representing an important stage of manufacture, in the country or territory in which the rules set out in that Annex are fulfilled or which is identified by those rules.”

For goods classified under Combined Nomenclature (CN) references not included in the above mentioned annex, the list rules adopted by the EC under the Harmonization Work Program are applicable. See the European Commission’s Taxation and Customs Union website for more information at https://ec.europa.eu/taxation_customs/home_en.

Links to specific product categories are provided at https://ec.europa.eu/taxation_customs/business/calculation-customs-duties/rules-origin/nonpreferential-origin/table-list-rules-applicable-products-following-classification-cn_en

COMMISSION IMPLEMENTING REGULATION (EU) 2018/775 of 28 May 2018 laying down rules for the application of Article 26(3) of Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers, as regards the **rules for indicating the country of origin or place of provenance of the primary ingredient of a food**

Article 1 – Scope

- “1. This Regulation lays down the modalities for the application of Article 26(3) of Regulation (EU) No 1169/2011 where the country of origin or place of provenance of a food is given by any means such as statements, pictorial presentation, symbols or terms, referring to places or geographical areas, except for geographic terms included in customary and generic names where those terms literally indicate origin but whose common understanding is not an indication of country of origin or place of provenance.
2. This Regulation shall not apply to geographical indications protected under Regulation (EU) No 1151/2012, Regulation (EU) No 1308/2013, Regulation (EC) No 110/2008 or Regulation (EU) No 251/2014 or protected pursuant to international agreements, nor registered trade marks where the latter constitute an origin indication, pending the adoption of specific rules concerning the application of Article 26(3) to such indications.”

Article 2 – Indication of the country of origin or place of provenance of the primary ingredient

“The country of origin or the place of provenance of a primary ingredient which is not the same as the given country of origin or the given place of provenance of the food shall be given:

- (a) with reference to one of the following geographical areas:
 - (i) ‘EU’, ‘non-EU’ or ‘EU and non-EU’; or
 - (ii) Region, or any other geographical area either within several Member States or within third countries, if defined as such under public international law or well understood by normally informed average consumers; or
 - (iii) FAO Fishing area, or sea or freshwater body if defined as such under international law or well understood by normally informed average consumers; or
 - (iv) Member State(s) or third country(ies); or
 - (v) Region, or any other geographical area within a Member State or within a third country, which is well understood by normally informed average consumers; or
 - (vi) The country of origin or place of provenance in accordance with specific Union provisions applicable for the primary ingredient(s) as such;
- (b) or by means of a statement as follows: ‘(name of the primary ingredient) do/does not originate from (the country of origin or the place of provenance of the food)’ or any similar wording likely to have the same meaning for the consumer.”

Article 3 – Presentation of the information

- “1. Information provided pursuant to Article 2 shall be provided in a font size which is not smaller than the minimum font size as required in accordance with Article 13(2) of Regulation (EU) No 1169/2011.
2. Without prejudice to paragraph 1, where the country of origin or place of provenance of a food is given with words, the information provided pursuant to Article 2 shall appear in the same field of vision as the indication of the country of origin or place of provenance of the food and by using a font size which has an x-height of at least 75% of the x-height of the indication of the country of origin or place of provenance of the food.
3. Without prejudice to paragraph 1, where the country of origin or place of provenance of a food is given by means of non-scriptural form, the information provided pursuant to Article 2 shall appear in the same field of vision as the indication of the country of origin or place of provenance of the food.”

Article 4 – Entry into force, date of application and transitional measures

This Regulation shall enter into force on the third day following that of its publication in the Official Journal of the European Union.

It shall apply from 1 April 2020.

Foods placed on the market or labelled prior to the date of application of this Regulation may be marketed until the stocks are exhausted.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

COMMISSION NOTICE 2020/C 32/01 on the application of the provisions of Article 26(3) of Regulation (EU) No 1169/2011

The purpose of this Commission notice is to provide guidelines for food business operators and national authorities on the application of the provisions of Article 26(3) of the Regulation.

This Notice should be read in conjunction with other relevant provisions of the Regulation and of the Implementing Regulation. In particular this guidance is without prejudice to the prohibition of misleading information to consumers provided for in Article 7 of the Regulation.

This Notice clarifies the provisions already contained in the applicable legislation. It does not extend in any way the obligations deriving from such legislation nor introduce any additional requirements on the concerned operators and competent authorities.

"2.4.1. Are terms such as 'made in', 'produced in' and 'product of' followed by a geographical statement to be considered as giving the country of origin or place of provenance of a food?

The statements such as 'made in (country)', 'manufactured in (country)', 'produced in (country)', are associated by consumers with an origin indication within the meaning of Article 26(3) and therefore, in principle, should be seen as indicating the country of origin or place of provenance of a food. In addition, those terms refer to production or manufacturing process, which, in the case of processed foods, could correspond to the meaning of the country of origin for the purposes of the Regulation, as defined in Article 60(2) of the Union Customs Code, i.e. the last substantial, economically-justified processing or working of a food, resulting in the manufacture of a new product or representing an important stage of manufacture.

Similarly, the statement 'product of (country)' in general implies for the consumer an origin indication within the meaning of Article 26(3) of the Regulation. In addition, the term 'product of' is also likely to suggest to the consumer that the entire food, including its ingredients, is coming from the country indicated on the label.

3.1. How the primary ingredient should be identified?

For the purpose of Article 26(3) of the Regulation, food business operators are required to provide information about the primary ingredient(s) of the food in question, on the basis of the definition laid down in Article 2(2)(q) of the Regulation.

The legal definition of the primary ingredient identifies two types of criteria to determine the primary ingredient of food: (a) a quantitative one, according to which the ingredient represents more than 50% of the food; and (b) a qualitative one, according to which the ingredient is usually associated by the consumers with the name of the food.

When providing information about the primary ingredient(s) of a food, food business operators should take into account various elements. In particular, in addition to quantitative composition of the food, they have to carefully consider its specific characteristics, nature and the entire presentation of the label. They also need to consider the consumers' perception and expectations with regard to the information provided about the food in question.

Food business operators should take into consideration whether the origin indication of a particular ingredient is likely to substantially affect consumers' purchasing decisions and whether the absence of such an origin indication would mislead consumers.

It is also to be mentioned that, in the spirit of Article 7 of the Regulation, the information provided with regard to the origin indication of the primary ingredient must not be misleading and in any event should not circumvent the provisions and objectives laid down in Article 26(3) of the Regulation.

Member States' competent authorities enforce the proper implementation of the above provisions of the Regulation.

- 3.2. Can a food have more than one primary ingredient? If yes, for the food that contains more than one primary ingredient, should the origin of all primary ingredients be given?

Article 2(2)(q) of the Regulation states in the definition of the 'primary ingredient' that the latter could be an ingredient (using the singular form of the word) or ingredients (using the plural form of the word). According to this wording, it should be concluded that the definition of the 'primary ingredient' provides for the possibility to have more than one primary ingredient of a food.

Furthermore, it is apparent from the provisions of Article 26(3) of the Regulation, that if the food business operator identifies, on the basis of the definition at hand, more than one primary ingredient, the country of origin or the place of provenance of all these primary ingredients must be indicated.

- 3.3. Is it possible that the application of the definition of the primary ingredient will result in no primary ingredient of a food?

For the purpose of Article 26(3) of the Regulation, it has to be first assessed whether any ingredient of a food is to be considered as its primary ingredient on the basis of the definition laid down in Article 2(2)(q) of the Regulation. This implies that a food will have no primary ingredient in the meaning of the Regulation where none of its ingredients represents more than 50% of that food, none of its ingredients is usually associated with the name of the food by the consumer and in most cases a quantitative indication is not required.

- 3.4. Does Article 26(3) of the Regulation and consequently the Implementing Regulation cover single ingredient products?

Article 26(3) of the Regulation could cover a processed single ingredient product, where its last substantial transformation occurred in a different place than the origin of the raw material ingredient or where the ingredient was sourced from different places. This situation would lead to the application of Article 26(3) of the Regulation in case the country of origin or place of provenance of the food is indicated and the country of origin or place of provenance of the primary ingredient (single ingredient), is not the same as that of the food."

DIRECTIVE 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements

Article 6

- “1. For the purposes of Article 5(1) of Directive 2000/13/EC, the name under which products covered by this Directive are sold shall be ‘food supplement’.
2. The labelling, presentation and advertising must not attribute to food supplements the property of preventing, treating or curing a human disease, or refer to such properties.
3. Without prejudice to Directive 2000/13/EC, the labelling shall bear the following particulars:
 - (a) the names of the categories of nutrients or substances that characterise the product or an indication of the nature of those nutrients or substances;”



Food Supplements Europe © December 2020

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