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# **GUIDANCE ON REGULATION (EU) 2017/2158**

# A) Food products referred to in Article 1(2)

(a) French fries, other cut (deep fried) products and sliced potato crisps from fresh potatoes;

This covers cut deep-fried and oven-baked products from fresh potatoes. This includes also potato products such as Rösti.

(b) potato crisps, snacks, crackers and other potato products from potato dough;

This covers potato crisps, potato snacks, potato crackers and other potato products from potato dough.

It covers deep-fried and oven-baked products.

It covers all potato products made from potato dough /puree such as pommes duchesse, croquettes, pommes noisettes, etc.;

In case of mixed doughs (mix of dough from potatoes and e.g. pulses), it is covered in case the potato dough constitutes > 50 %.

(c) bread;

This covers all ordinary bakery wares like bread (e.g. wheat bread, rye bread, whole meal bread, multi grain bread, malt bread, pumpernickel bread), rolls (hamburger rolls, whole wheat rolls, milk rolls), bagels, pita bread, Mexican tortillas and steamed breads. It also covers baguettes, ...

(d) breakfast cereals (excluding porridge);

This covers all ready-to-eat, instant and regular hot breakfast cereal products, including rolled cereals. Examples include: granola-type breakfast cereals, corn flakes, puffed wheat or rice, multi-grain (e.g. rice, wheat and corn) breakfast cereals, mueslis, breakfast cereals made from soy or bran, and extruded-type breakfast cereals made from grain flour or powder.

(e) fine bakery wares: cookies, biscuits, rusks, cereal bars, scones, cornets, wafers, crumpets and gingerbread, as well as crackers, crisp breads and bread substitutes. In this category a cracker is a dry biscuit (a baked product based on cereal flour);

This covers sweet, salty and savoury products, such as cookies, doughnuts, biscuits, rusks, cereal bars, scones, cornets, wafers, crumpets, pancakes, gingerbread, pretzels, croissants, as well as unsweetened products such as crackers, crisp breads and bread substitutes. In this category a cracker is a dry biscuit (baked product based on cereal flour), e.g. soda crackers, ...

This category also includes rice crackers, rye crisps, matzo etc ...

(f) coffee(i) roast coffee;

This covers product prepared by roasting, grinding, or both roasting and grinding, coffee beans (Coffea arabica or Coffea robusta). Available as roasted coffee beans or ground coffee.

(ii) instant (soluble) coffee;

This means the concentrated product obtained by extraction from roasted coffee beans using only water as the medium of extraction and excluding any process of hydrolysis involving the addition of an acid or a base. Apart from those insoluble substances which it is technically impossible to remove, and insoluble oils derived from coffee, coffee extract must contain only the soluble and aromatic constituents of coffee.

Coffee extract in solid or paste form must contain no substances other than those derived from the extraction of coffee.

Liquid coffee extract may contain edible sugars, whether or not roasted, in a proportion not exceeding 12% by weight.

#### (g) coffee substitutes;

These are non-coffee products, usually without caffeine, that are used to imitate/replace coffee. They are typically extracted from plant-based substances such as grains (e.g. barley, rye, etc.), plant roots (e.g. chicory, dandelion, beetroot, etc.) and molasses. The plant material may be roasted prior to processing to a soluble extract. Coffee substitutes may be sold as plain liquid extract and/or instant powder or granules; it may be made of several plant-based substances or blended with coffee extracts and it may be flavoured.

Roasted grain beverages are common coffee substitutes. A roasted grain beverage is a beverage made from one or more cereal grains roasted and commercially processed into granular or powder form to be reconstituted later in water. The product is often marketed as a caffeine-free alternative to coffee and tea. Some common ingredients include toasted/malted barley, rye, etc.

Ground roasted chicory root is used as a coffee substitute product, both alone and mixed with coffee. 'Chicory' means the roots of Cichorium Intybus L., not used for the production of witloof chicory, usually used for the preparation of beverages, suitably cleaned to be dried and roasted. 'Chicory extract', 'soluble chicory' or 'instant chicory' means the concentrated product obtained by extraction from roasted chicory using only water as the medium of extraction and excluding any process of hydrolysis involving the addition of an acid or a base.

Chicory extract in solid or paste form may contain no more than 1% by weight of substances not derived from chicory.

Liquid chicory extract may contain edible sugars, whether roasted or not, to a proportion not exceeding 35% by weight.

There are several different types of coffee substitutes: mixture of barley, rye, chicory, and fig; mixture of roasted barley, malted barley, chicory and rye; mixture of roasted barley, roasted barley malt and roasted chicory; mixture of barley, chicory, malted barley, figs, and extract of red beets; postum (made from roasted wheat bran, wheat and molasses), malt-based flavoured drinks, etc.

(h) baby food and, processed cereal-based food intended for infants and young children as defined in Regulation (EU) No 609/2013 of the European Parliament and of the Council.

**'baby food'** means food intended to fulfil the particular requirements of infants in good health while they are being weaned, and of young children in good health as a supplement to their diet and/or for their progressive adaptation to ordinary food, excluding:

(i) processed cereal-based food; and

(ii) milk-based drinks and similar products intended for young children;

### 'processed cereal-based food' means food

(i) intended to fulfil the particular requirements of infants in good health while they are being weaned, and of young children in good health as a supplement to their diet and/or for their progressive adaptation, to ordinary food; and (ii) pertaining to one of the following categories:

- simple cereals which are or have to be reconstituted with milk or other appropriate nutritious liquids,

- cereals with an added high protein food which are or have to be reconstituted with water or other protein-free liquid,

- pastas which are to be used after cooking in boiling water or other appropriate liquids,

 rusks and biscuits which are to be used either directly or, after pulverisation, with the addition of water, milk or other suitable liquids;

Products of which can be clearly deduced from the packaging or from instructions/information provided on the packaging that the products are destined for infants and young children fall also within this category.

# B) Food businesses referred to in Article 2 (1) (2), (3)

Article 2(1): relates to food business operators, which produce and place on the market foodstuffs, listed in Article 1(2) (with the exception of the food business operators referred to in Article 2(2) and 2(3)

RELEVANT EUROPEAN STAKEHOLDER ORGANISATIONS: FDE (FoodDrinkEurope) and relevant branch organisations: - CAOBISCO - Association of Chocolate, Biscuit and Confectionery Industries of the European Union - CEEREAL - European Breakfast Cereal Association - ECF - European Coffee Federation - ESA - European Snacks Association - EUPPA - European Potato Processors' Association - FEDIMA - Federation of EU Manufacturers and Suppliers of Ingredients to the Bakery, Confectionary and Patisserie Industries - SNE: Specialised Nutrition Europe AIBI asbl: International Association of Plant Bakers

# Article 2(2) Food business operators producing foodstuffs listed in Article 1(2), which perform retail activities, and/or directly supply only local retail establishments

Retail: means the handling and/or processing of food and its storage at the point of sale or delivery to the final consumer, and includes distribution terminals, catering operations, factory canteens, institutional catering, restaurants and other similar food service operations, shops, supermarket distribution centres and wholesale outlets;

Final consumer: means the ultimate consumer of a foodstuff who will not use the food as part of any food business operation or activity.

<u>RELEVANT EUROPEAN STAKEHOLDER ORGANISATIONS</u>: UEAPME (European Association of craft, small and medium-sized enterprises), HOTREC (Umbrella association for hotels, restaurants, cafés and similar establishments in Europe), FoodServiceEurope (European contract catering sector), Eurocommerce (retail and wholesale sector in Europe)

It relates to establishments handling and/or processing of food at the point of sale or delivery to the final consumer- typically small scale operators For the determination if a food business operator falls within this category following <u>criteria can be used as guidance</u>:

- it concerns companies falling within the definition of micro-enterprises (for the hotel sector this would relate to the catering part of the company). Some flexibility can be applied for food business operators falling within the definition of small enterprises and just not falling within the definition of microenterprises (<u>http://ec.europa.eu/growth/smes/business-friendly-environment/smedefinition\_en</u>)

- Local: supply to other retail establishments only within e.g. 100km of the supplying establishment.

- Other criteria which could be applied are the ratio in turn-over between selling directly to the final consumer and supply to other local retail establishments, the number of other local retail establishments supplied etc. Article 2(3) Food business operators producing foodstuffs listed in Article 1(2), which perform retail activities, and/or directly supply only local retail establishments and which operate in facilities under direct control and that are operating under one trademark or commercial license, as a part of, or franchise of, a larger, interconnected operation and under the instructions of the food business operator that centrally supplies the foodstuffs

<u>RELEVANT EUROPEAN STAKEHOLDER ORGANISATION</u>: Serving Europe (Branded Food and Beverage Service Chains Association)

The food business operators covered by this category are typically large, centrally controlled and centrally supplied chains with standardised menus and same standard operating procedures in all facilities of the food business operator

#### Remark as regards food business operators performing different activities.

In case a food business operator produce foodstuffs falling under different categories of foods within the scope of the Regulation (see Article 1(2)) and the food business operator <sup>2</sup>would for one activity fall under category 2(1) as food business operator and for another activity fall under category 2(2) as food business operator, such a food business operator is obliged to apply the mitigation measures referred to in Annex I of the Regulation and to fulfil the requirements as regards sampling and analysis as referred to in Annex III for all his activities falling within the scope of the Regulation.

# C) Benchmark levels

'benchmark levels' are performance indicators used to verify the effectiveness of the mitigation measures and are based on experience and occurrence for broad food categories. The benchmark level cannot be directly used as reference to evaluate if a product can be placed on the market or not.

When the benchmark levels are exceeded, food business operators shall review without delay the mitigation measures applied and adjust processes and controls with the aim to achieve levels of acrylamide as low as reasonable achievable below the benchmark levels set (obligations for food business operators referred to in Article 2(1) and 2(3). This must be demonstrated by the undertaking of a new representative sampling and analysis, after the introduction of the additional mitigation measures.

The benchmark levels have been established for broad food categories. It is to be acknowledged that for specific foods within such a broad food category there could be specific production, geographic or seasonal conditions or product characteristics for which it is not possible to achieve the benchmark levels, despite the application of all relevant mitigation measures. In such situations, the food business operator should be able to show the evidence that he applied the relevant mitigation measures.

Furthermore it has to be stressed the application of mitigation measures and benchmark levels should, not result in a prohibition of certain traditional culinary practices and/or certain traditional foods. Food business operators are obliged to apply mitigation measures and benchmark levels with respect to the culinary practices and the recipe of traditional foods (i.e. choosing for those options which result in a level of acrylamide as low as reasonably achievable) without changing the nature and the organoleptic characteristics of the traditional food.

# D)Safety of food products related to the presence of acrylamide

In case a very high level of acrylamide is found in a certain food, this food cannot be placed on the market, in application of the article 14 of the General Food Law 178/2002. An exceedance of the benchmark level does not necessarily result in being the food unsafe.

# E) Application of mitigation measures (Annexes I and II)

a) Mitigation measures have to be applied by food business operators, which produce and place on the market foodstuffs (Article 1 (1)).

If the producer and distributor of the food are not the same food business operator, the mitigation measures provided for in Annexes have to be applied by the producer and not by the distributor.

## b) Information for end users on the packaging:

Food business operators are authorised to market the products made before 11 April 2018 until the exhaustion of the stocks and to use the packaging produced before 11 April 2018 until exhaustion of the stocks.

# c) Clarifications as regards food categories in Annex I (see also section A of this guidance document)

<u>References to the scope in Article 1(2) have to be read in connection with the</u> <u>information provided in section A of this guidance document</u>

I. <u>Products based on raw potatoes</u>

Refers to products covered by Article 1 (2) (a)

# II. <u>Dough based potato crisps, snacks, crackers and other dough based</u> <u>potato products</u>

Refers to dough based potato crisps, potato snacks, potato crackers and other dough based potato products covered by Article 1 (2) (b)

III. <u>Fine bakery wares</u> Refers to products covered by Article 1 (2) (e)

#### IV. Breakfast cereals

Refers to products covered by Article 1 (2) (d)

### V. <u>Coffee</u>

Refers to products covered by Article 1 (2) (f) <sup>2</sup>

VI. <u>Coffee substitutes containing more than 50% cereals</u>

VII. <u>Coffee substitutes containing more than 50 % chicory</u> Refers to products covered by Article 1 (2) (g)

### VIII. Baby biscuits and infant cereals

Refers to processed cereal-based food intended for infants and young children covered by Article 1 (2) (h) and includes also cereal-based products of which can be clearly deduced from the packaging or from instructions/information provided on the packaging that the products are destined for infants and young children.

### IX. <u>Baby jar foods (low acid and prune based foods)</u>

Refers to baby food covered by Article 1 (2) (h) and includes also products of which can be clearly deduced from the packaging or from instructions/information provided on the packaging that the products are destined for infants and young children. It does include not only baby foods in jar "sensu stricto", but also baby foods sold in plastic pots, bags etc...

#### X. <u>Bread</u>

Refers to products covered by Article 1 (2) (c)

# d) Food business operators referred to in Article 2(2) have to apply the mitigation measures provided for in Article II part A

It is to be noted that certain food business operator fall within Article 2(2) but for which no mitigation measures are provided for in Annex II part A, e.g. food business operators roasting on a small scale coffee for selling directly to the consumer in their shop. Consequently, for these food business operators there is no legal obligation to apply mitigation measures.

# F) Sampling and analysis

Food business operators (FBOs) referred to in Article 2(1) and 2(3) shall perform sampling and analysis to determine the level of acrylamide in foodstuffs in accordance with the requirements set out in Annex III to this Regulation and shall record the results of the sampling and analysis.

# The obligation to perform sampling and analysis does not apply to Food business operators referred to in Article 2(2)

FBOs shall ensure that a representative sample of **each product type** is taken for analysis of acrylamide concentration. A "product type" includes groups of products with the same or similar ingredients, recipe design, process design and/or process controls where these have a potential influence acrylamide levels in the finished product. Monitoring programmes shall prioritise product types that have the demonstrated potential to exceed the benchmark level and shall select the product within a product type that within a product type is known/assumed to contain the highest levels of acrylamide and shall be risk-based where further mitigation measures are feasible.

The sample shall be representative for the sampled batch.

FBOs shall ensure that they undertake representative sampling and analysis of their products for the presence of acrylamide to verify the effectiveness of mitigation measures, i.e. the levels of acrylamide are consistently below the benchmark levels.

→ Food business operator has to be able to justify the selection of the product within a product type for sampling

## Frequency of sampling

FBOs shall, undertake sampling and analysis <u>at least annually for products that</u> have a known and **well-controlled acrylamide level**.

- → no seasonal variation (in case of seasonal variation, sample has to be taken when level of acrylamide is expected to be the highest.
- ➔ In case of changing a supply of an ingredient/raw material which is known to influence the level of acrylamide, a representative sample must be taken to ensure/verify that level of acrylamide remains below benchmark level

FBOs shall carry out <u>higher frequency sampling and analysis of products</u> <u>having the potential to exceed the benchmark level</u> and shall be risk-based where further mitigation measures are feasible.

→ FBOs shall specify appropriate frequencies for analysis for each product type. If a product or process is modified in a way that could lead to a change in the acrylamide level in the final product → adapted frequency of sampling to be determined.

In case of exceedance of the benchmark level (corrected for recovery but not taking the measurement uncertainty), FBOs shall carry out a review of the mitigation measures applied and shall take additional available mitigation measures to ensure that acrylamide level in the finished product is below the benchmark level. This must be demonstrated by the undertaking of a new representative sampling and analysis, after the introduction of the additional mitigation measures.

For food business operators referred to in Article 2(3) it is sufficient that the FBOs carry out tests on samples of deep fried/ oven-baked potato products and bakery products at centralised level (not in individual stores) whereby the food has been prepared under practical conditions according to the standard operating procedure (SOP) because these FBOs use standardised procedures for processing and cooking products with the precise objective of serving standardised food offerings to customers, notably as concerns deep fried/ oven-baked potato and bakery products.

Taking into consideration the highly standardised and controlled procedures that characterise the operations of the FBOs referred to under Article 2(3), it is sufficient to measure the acrylamide level in samples of deep fried/oven-baked potato products and bakery products once per year, unless during a calendar year a key factor comes to light that is likely to impact the acrylamide level in relevant products (e.g. in the event of introduction of a new or adapted recipe or cooking procedure).

# Statistical correlation to be demonstrated between product attributes or process parameters and the acrylamide level (Annex III, point 4)

Statistical correlation shows whether and how strongly pairs of variables are related. The number of analysis to be performed to demonstrate this correlation depends on the variability of the analytical results. In case the acrylamide level related to a product attribute (e.g. a specific colour) is constant (i.e. not variable, within a small range of variation), then e.g. 3-5 analysis can be sufficient to demonstrate this correlation. In case of larger variation more analysis might be needed.

This correlation can be demonstrated and provided by the central supplier and does in that case not need to be performed by the individual food business operators as end user (e.g. bake-off areas).

# G) <u>Record keeping and information to competent</u> <u>authorities</u>

Food business operators referred to in Article 2(1) shall keep a record of the applied mitigation measures set out in Annex I of the Regulation and food business operators referred to in Article 2(3) shall keep a record of the applied mitigation measures set out in Part A and B of Annex II.

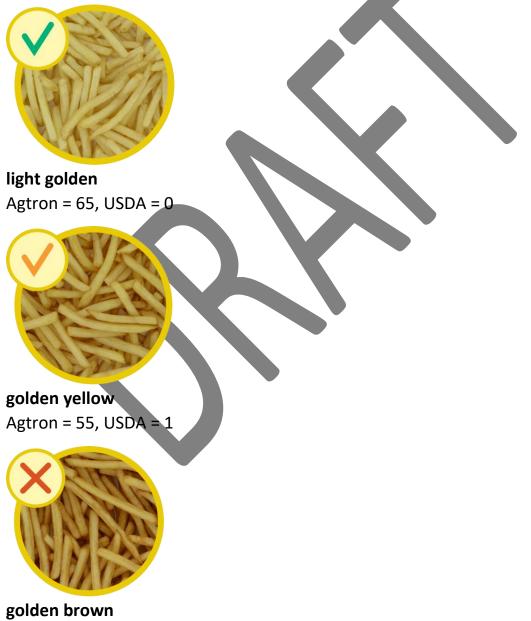
These Food business operators shall make the analytical results obtained from the analysis every year available on request to the competent authority together with descriptions of the products analysed. Details of mitigation measures taken to reduce levels of acrylamide below the benchmark level shall be provided for those products exceeding the benchmark level.

Food business operators referred to in Article 2(2) does not have to keep records of the applied mitigation measures but have to be able to provide evidence of being aware and of the application of mitigation measures set out in part A of Annex II. This requirement to provide evidence does not necessarily imply documentation obligations but any other type of evidence is sufficient to fulfil this obligation (e.g. by showing the temperature set for frying, etc...)

# H) Colour guides

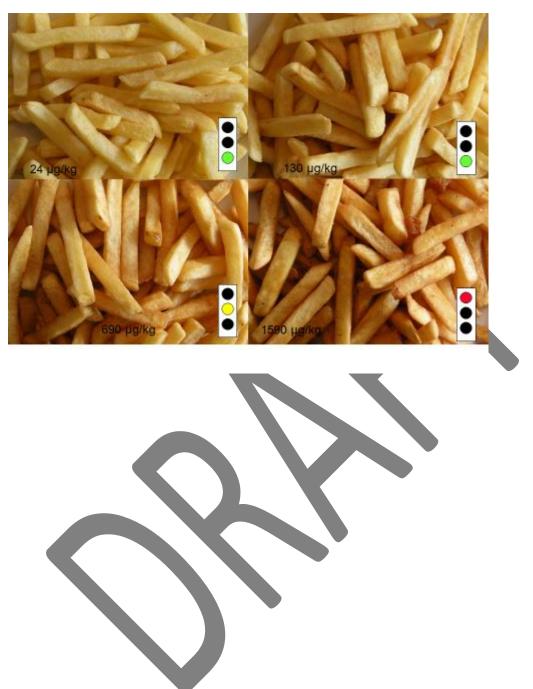
For food business operators referred to in Article 2(2) and 2(3), <u>the use and</u> <u>display of colour guides for the cooking of French fries and preparing</u> <u>sandwiches is a strong recommendation but not an obligation for the food</u> <u>business operators.</u>

For French fries: the colour guide available at <a href="http://goodfries.eu/en/home/">http://goodfries.eu/en/home/</a> can be used as reference.



Agtron = 40, USDA = 2

Another example of colour guide:



# I) Benchmark levels (Annex IV)

**IMPORTANT REMARK:** The benchmark levels have been established for broad food categories. It is to be acknowledged that for specific foods within such a broad food category there could be specific production, geographic or seasonal conditions or product characteristics for which it is not possible to achieve the benchmark levels, despite the application of all relevant mitigation measures. In such situations, the food business operator should be able to show the evidence that he applied the relevant mitigation measures.

<u>References to the scope in Article 1(2) have to be read in connection with the</u> <u>information provided in section A of this guidance document</u>

#### French fries (ready-to-eat) - benchmark level 500 µg/kg

The benchmark level is also applicable to other cut deep-fried and oven baked products from fresh potatoes including potato products such as potato Rösti. (foods referred to in Article 1 (2) (a) with the exception of sliced potato crisps from fresh potatoes)

Potato crisps from fresh potatoes and from potato dough / potato based crackers / other potato products from potato dough - benchmark level 750  $\mu$ g/kg

The benchmark level is applicable to all the products referred to in Article 1(2)(b) and sliced potato crisps from fresh potatoes referred to in Article 1(2)(c)

#### Soft bread - wheat based bread - benchmark level 50 µg/kg

The benchmark level is applicable to wheat-based bread referred to in Article 1 (2) (c). Wheat based bread is bread of which the cereal ingredient is at least or equal to 50 % of wheat (or wheat derived product).

# Soft bread – soft bread other than wheat based bread – benchmark level 100 $\mu g$

The benchmark level is applicable to soft bread other than wheat-based bread referred to in Article 1 (2) (c), i.e. all bread of which wheat (or wheat derived products) constitutes less than 50 % of the cereal ingredient.

### Breakfast cereals (excluding porridge)

This category refers to the products referred to in Article 1(2)(d).

Breakfast cereals produced under high temperature conditions such as toasted and gun-puffed breakfast cereals contain higher levels of acrylamide (without having the possibility to apply additional mitigation measures to obtain lower levels of acrylamide) than other breakfast cereals such as muesli, crunchy muesli and granola.

# Breakfast cereals (excluding porridge) – bran products and whole grain cereals, gun puffed grain – benchmark level of 300 $\mu$ g/kg

Includes all breakfast cereals based on bran products and/or whole grain cereals or gun puffed grain (independently from the type of grain of which the breakfast cereal is produced).

# Breakfast cereals (excluding porridge) – wheat and rye based products - benchmark level of $300 \,\mu\text{g/kg}$

Refers to <u>non-whole grain</u> and/or <u>non-bran based</u> breakfast cereals (also breakfast cereals based on gun puffed grain are not included in this category). The cereal present in the largest quantity determines the category. So the breakfast cereal is wheat or rye based in case wheat or rye are the cereal present in the largest quantity.

# Breakfast cereals (excluding porridge) – maize, oat, spelt, barley and rice based products - benchmark level of 150 $\mu$ g/kg

Refers to <u>non-whole grain</u> and/or <u>non-bran based</u> breakfast cereals (also breakfast cereals based on gun puffed grain are not included in this category). The cereal present in the largest quantity determines the category.

# Biscuits and wafers, crackers with the exception of potato based crackers, crispbread, ginger bread and products similar to the other products in this category.

These products /product groups refer to the fine bakery wares referred to in Article 1 (2) (e). Hereafter the different products falling under the fine bakery wares are classified under the different product groups within the group of fine bakery wares

### Biscuits and wafers – benchmark level of 350 $\mu$ g/kg

Besides biscuits and wafers, this product group includes also rusks, cookies, cornets, ... (it does not include the biscuits and rusks intended for infants and young children referred to in Article 1 (2) (h))

# Crackers with the exception of potato based crackers $\,$ - benchmark level of 400 $\mu g/kg$

Crackers which are a dry biscuit (baked product based on cereal flour) e.g. soda crackers, pretzel crackers, ...

### Crispbread – benchmark level of 350 µg/kg

Crispbread, rye crisps, ... (for regional names: see <u>https://en.wikipedia.org/wiki/Crispbread</u>)

#### Gingerbread – benchmark level of 800 $\mu$ g/kg

Gingerbread refers to a broad category of baked goods, typically flavoured with ginger, clove, nutmeg or cinnamon sweetened with honey, sugar or molasses. Gingerbread foods vary, ranging from a soft, moist loaf cake to something close to a ginger biscuit (for regional names: see <u>https://en.wkipedia.org/wiki/Gingerbread</u>)

#### Products similar to the other products in this category

This product group includes doughnuts, cereal bars, scones, crumpets, pancakes, croissants, rice crackers, matzo, ...

This product group includes also bread substitutes not yet mentioned and not covered by any other product group under fine bakery wares.

### Roast coffee – benchmark level of 400 $\mu$ g/kg

This category refers to the products referred to in Article 1(2)(f) (i).

### Instant (soluble) coffee – benchmark level of 850 $\mu$ g/kg

This category refers to the products referred to in Article 1(2)(f) (ii).

#### **Coffee substitutes**

This category refers to the products referred to in Article 1(2)(g).

Coffee substitutes exclusively from cereals – benchmark level of 500  $\mu$ g/kg

Coffee substitutes exclusively from chicory – benchmark level of 4000  $\mu\text{g}/\text{kg}$ 

#### Coffee substitutes from a mixture of cereals and chicory

The applicable benchmark level to these coffee substitutes takes into account the relative proportion of the ingredients in the final product

## Mixture of coffee with coffee substitutes

The applicable benchmark level to these mixtures takes into account the relative proportion of the ingredients in the final product

Baby foods, processed cereal based foods for infant and young children excluding biscuits and rusks - benchmark level of 40 µg/kg

This category refers to the products referred to in Article 1(2)(h).

Refers to baby food and processed cereal based foods (excluding biscuits and rusks) as defined in Regulation (EU) No 609/2013

Products of which can be clearly deduced from the packaging or from instructions/information provided on the packaging that the products are destined for infants and young children fall also within this category.

# Biscuits and rusks for infant and young children - benchmark level of 150 $\mu\text{g}/\text{kg}$

This category refers to the products referred to in Article 1(2)(h).

Refers to biscuits and rusks (processed cereal based foods) as defined in Regulation (EU) No 609/2013

Products of which can be clearly deduced from the packaging or from instructions/information provided on the packaging that the products are destined for infants and young children fall also within this category.