



EUROPEAN
COMMISSION

Brussels, **XXX**
SANTE/11059/2016 ANNEX Rev. 3
(POOL/E2/2016/11059/11059R3-EN
ANNEX.doc) D048379/05
[...](2017) **XXX** draft

ANNEXES 1 to 4

ANNEXES

to the

COMMISSION REGULATION (EU) .../...

**establishing mitigation measures and benchmark levels for the reduction of the presence
of acrylamide in food**

ANNEX I

MITIGATION MEASURES REFERRED TO IN ARTICLE 2(1)

Where the mitigation measures in this Annex include the use of food additives and other substances, the food additives and other substances shall be used in accordance with the provisions provided for in Regulations (EC) No 1332/2008¹, (EC) 1333/2008² and (EU) No 231/2012³.

I. PRODUCTS BASED ON RAW POTATOES

Selection of suitable potato varieties

1. Food business operators (hereinafter 'FBOs') shall identify and use the potato varieties that are suitable for the product type and where the content of acrylamide precursors, such as reducing sugars (fructose and glucose) and asparagine is the lowest for the regional conditions.
2. FBOs shall use the potato varieties which have been stored in the conditions which are applicable to a specific potato variety and for the storage period determined for a specific variety. The stored potatoes shall be used within their optimal storage window.
3. FBOs shall identify potato varieties with lower acrylamide forming potential in cultivation, storage and during food processing. The results shall be documented.

Acceptance criteria

1. FBOs shall specify in their arrangements regarding potato supply the maximum content of reducing sugars in potatoes and also the maximum amount of bruised, spotted or damaged potatoes.
2. If the specified content of reducing sugar content in potatoes and the amount of bruised, spotted or damaged potatoes are exceeded, FBOs may accept the potato supply by specifying additional available mitigation measures to be taken to ensure that the presence of acrylamide in the final product is as low as reasonably achievable below the benchmark level set out in Annex IV.

Potato storage and transport

1. Where FBOs operate their own storage facilities:
 - the temperature shall be appropriate to the potato variety stored and it shall be above 6°C;
 - the level of humidity shall be such as to minimise senescent sweetening;

¹ Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) 258/97 (OJ L 354, 31.12.2008, p. 7).

² 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).

³ Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).

- sprouting shall be suppressed in long term stored potatoes where permitted, using appropriate agents;
 - during storage the level of reducing sugars in potatoes shall be tested.
2. Potato lots shall be monitored for reducing sugars at the time of harvest.
 3. FBOs shall specify the potato transport conditions in terms of temperature and duration especially if outside temperatures are significantly lower than the temperature regime applied during storage, to ensure that the temperature during the transportation of potatoes is not lower than the temperature regime applied during storage. These specifications shall be documented.

(a) SLICED POTATO CRISPS

Recipe and process design

1. For each product design, FBOs shall specify frying oil temperatures at the exit of the fryer. Those temperatures shall be as low as feasibly possible on a specific line and for the specific product, in line with quality and food safety standards and taking into account relevant factors such as fryer manufacturer, fryer type, potato variety, total solids, potato size, growing conditions, sugar content, seasonality and the target moisture content for the product.
2. Where the frying oil temperatures at the exit of the fryer is higher than 168°C due to a specific product, design or technology, then the FBOs shall provide data demonstrating that the level of acrylamide in the finished product is as low as reasonably achievable and that the benchmark level set out in Annex IV is achieved.
3. For each product design, FBOs shall specify the moisture content post frying which shall be set as high as feasibly possible for a specific production line and for a specific product, in accordance with expected quality and food safety standards and taking into account relevant factors such as potato variety, seasonality, tuber size, and the fryer exit temperature. The minimal moisture content shall not be lower than 1.0%.
4. FBOs shall use in-line colour sorting (manual and/or optical-electronic) for potato crisps post frying.

(b) FRENCH FRIES AND OTHER CUT DEEP FRIED OR OVEN-FRIED POTATO PRODUCTS

Recipe and Process design

1. Potatoes shall be tested for reducing sugars prior to use. This can be done by fry testing using colours as an indicator of potential high reducing sugar content: indicative fry testing 20-25 centre strips, which are fried to evaluate frying colours of the potato strips against the colour specification using a USDA Munsell colour chart or calibrated company-specific charts for small operators. Alternatively the overall finished frying colour can be measured by specific equipment (e.g. Agtron).
2. FBOs shall remove immature tubers having a low underwater weight and high reducing sugar levels. The removal can be done by passing tubers through a salt brine or similar systems which make immature tubers float or by pre-washing potatoes to detect bad tubers.

3. FBOs shall remove slivers right after cutting to avoid burned pieces in the final cooked product.
4. FBOs shall blanch potato strips to remove some of the reducing sugars from the outside of the strips.
5. FBOs shall adapt blanching regimes to the specific quality attributes of the incoming raw material and they shall stay within specification limits for finished product colour.
6. FBOs shall prevent (enzymatic) discolouration and after cooking darkening of potato products. This can be done by applying disodium diphosphate (E450), which also lowers the pH level of the washing water and inhibits the browning reaction.
7. The use of reducing sugars as a browning agent shall be avoided. They may be used only if needed, to consistently stay within specification limits. FBOs shall control the colour of the final product by performing colour checks on the final cooked product. If needed after blanching, controlled addition of dextrose enables meeting the finished colour specification. Controlled addition of dextrose after blanching results in lower acrylamide levels in the final cooked product at the same colour as observed in unblanched products with only naturally accumulated reducing sugars.

Information to the end users

1. For the end users, FBOs shall indicate recommended cooking methods specifying time, temperature, quantity for oven/ deep fryer/ pan on packaging and/or via other communication channels. For consumers the recommended cooking instructions shall be clearly displayed on all product packaging in compliance with Regulation 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers⁴.

Recommended cooking methods shall be in agreement with customer specifications and requirements for professional end users and must be validated per product type to ensure products have optimal sensory quality at the lightest acceptable colour, per cooking method specified (e.g. fryer, oven) and have levels of acrylamide below the benchmark level determined in Annex IV.

FBOs shall recommend to end users other than consumers that they should have tools available for the operators (e.g. chefs) to ensure good cooking methods and also provide calibrated equipment (e.g. timers, frying curves, colour grading charts (e.g. USDA/Munsell) and at minimum, clear pictures with targeted final prepared product colours.

⁴ 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.

2. FBOs shall recommend the end users in particular to:
 - keep the temperature between 160 and 175°C when frying, and 180-220°C when using an oven. Lower temperature can be used when the fan is switched on;
 - Preheat the cooking device (e.g. oven, air fryer) to correct temperature between 180-220°C according to on-pack cooking instructions, depending on the products specifications and local requirements;
 - cook potatoes until a golden yellow colour;
 - do not overcook;
 - turn oven products after 10 minutes or halfway through the total cooking time;
 - follow the recommended cooking instructions, as provided by the manufacturer;
 - when preparing smaller quantities of potatoes than indicated on pack, reduce the cooking time, to avoid excessive browning of the product;
 - do not overfill the frying basket; fill your basket up to the halfway mark to avoid excessive oil uptake by extended frying times.

II. DOUGH-BASED POTATO CRISPS, SNACKS, CRACKERS AND OTHER DOUGH-BASED POTATO PRODUCTS

Raw Materials

1. For each product, FBOs shall specify target values for reducing sugars in their dehydrated potato ingredients.
2. The target value of reducing sugars in the products concerned shall be set as low as feasibly possible, taking into account all relevant factors in the design and production of the finished product such as the amount of potato ingredients in the product recipe, further possible mitigation measures, further processing of the dough, seasonality and the moisture content in the finished product.
3. Where the content of reducing sugars is higher than 1.5% the FBOs shall provide data demonstrating that the level of acrylamide in the finished product is as low as reasonably achievable below the benchmark level set out in Annex IV.

Recipe and Process Design

1. Dehydrated potato ingredients shall be analysed prior to their use either by the supplier or the user to confirm that the sugar content does not exceed the specified level.
2. Where dehydrated potato ingredients exceed the specified sugar level, FBOs shall specify the additional mitigation measures to be taken to ensure that the level of acrylamide in the final product is as low as reasonably achievable below the benchmark level set out in Annex IV.

3. For each product FBOs shall review whether it is possible to utilise the partial replacement of potato ingredients with ingredients with lower acrylamide forming potential.
4. In wet dough-based systems, FBOs shall consider the use of the following substances insofar possible, taking into account that these substances may not be synergistic in their mitigation effect i.e. specifically applies to the use of asparaginase and lowering levels of pH:
 - Asparaginase
 - Acids or their salts (to reduce the level of pH of the dough)
 - Calcium salts.
5. Where dough-based potato crisps, snacks or crackers are fried, FBOs shall specify frying oil temperatures for each product at the exit of the fryer, control these temperatures and maintain records to demonstrate controls.
6. The oil temperature at the fryer exit shall be as low as feasibly possible on a specific line and for the specific product, in accordance with prescribed quality and food safety standards and taking into account relevant factors, such as the fryer manufacturer, fryer type, sugar content and the target moisture content for the product.

Where the temperature is higher than 175°C at the fryer exit, FBOs shall provide data demonstrating that the level of acrylamide in the finished product is below the benchmark level specified in Annex IV.

(Note: Most pellet products are fried at temperatures higher than 175 °C because of their very short frying time and the temperatures needed to achieve the required expansion and texture of these products).
7. Where dough-based potato crisps, snacks or crackers are baked, FBOs shall specify for each product the baking temperature at the exit of the baking oven and maintain records to demonstrate controls.
8. The temperature at the exit of the baking oven /drying process shall be as low as feasibly possible on a specific line and for the specific product, in line with expected quality and food safety standards, and taking into account relevant factors such as the machinery type, reducing sugar content of the raw material and the moisture content of the product.
9. Where the product temperature is higher than 175°C at the end of the baking/drying process, the FBOs shall provide data demonstrating that the level of acrylamide in the finished product is below the benchmark level specified in Annex IV.
10. For each product, FBOs shall specify the moisture content post frying or baking which shall be set as high as feasibly possible on a specific production line and for a specific product, in line with the product quality and food safety requirements, and taking into account the fryer exit, baking and drying temperature. The moisture content in the final product shall not be lower than 1.0%.

III. FINE BAKERY WARES

The mitigation measures in this Chapter are applicable to the fine bakery wares such as cookies, biscuits, rusks, cereal bars, scones, cornets, wafers, crumpets and gingerbread, as well as unsweetened products such as crackers, crisp breads and bread substitutes. In this category a cracker is a dry biscuit (a baked product based on cereal flour), e.g. soda crackers, rye crispbreads and matzot.

Agronomy

In case of contract farming, where agricultural products are supplied to FBOs directly by their producers, FBOs shall ensure that the following requirements to prevent elevated asparagine levels in cereals are applied:

- to follow Good Agricultural Practices on fertilisation, in particular with regard to maintaining balanced sulphur levels in the soil and to ensure a correct nitrogen application;
- to follow Good Phytosanitary Practices in order to ensure the application of good practices on crop protection measures to prevent fungal infection.

FBOs shall carry out controls to verify the effective application of the aforesaid requirements.

Recipe and Product Design

In the manufacturing process FBOs shall apply the following mitigation measures:

1. For relevant products, FBOs shall consider reducing or replacing fully or partially ammonium bicarbonate with alternative raising agents such as
 - (a) sodium bicarbonate and acidulants, or
 - (b) sodium bicarbonate and disodium diphosphates with organic acids or potassium variants thereof.

As part of this consideration, FBOs shall ensure that the use of the said alternative raising agents do not result in organoleptic changes (taste, appearance, texture etc.) or increase the overall sodium content which influence product identity and consumers acceptance.

2. For products where the product design allows, FBOs shall replace fructose or fructose-containing ingredients such as syrups and honey with glucose or non-reducing sugars such as sucrose, particularly in recipes containing ammonium bicarbonate where possible and taking into consideration that replacing fructose or other reducing sugars may result in a modified product identity due to loss of flavour and colour formation.
3. FBOs shall use asparaginase where effective and possible to reduce asparagine and mitigate the potential for acrylamide formation. FBOs shall take into account that there is limited or no effect on the levels of acrylamide of the use of asparaginase in recipes with high fat content, low moisture or high pH value.
4. Where a product characteristic allows, FBOs shall review whether it is possible to utilise the partial replacement of wheat flour with alternative grain flour, such as rice, taking into consideration that any change will have an impact on the baking process and organoleptic properties of the products. Different types of grains have shown different levels of asparagine (typical asparagine levels

are the highest in rye and in descending order lower in oats, wheat, maize and with the lowest levels in rice).

5. FBOs shall take into account in the risk assessment the impact of ingredients in the fine bakery wares that may raise acrylamide levels in the final product, and use ingredients that do not have such effects but maintain physical and organoleptic properties (such as almonds roasted at lower rather than higher temperatures and dried fruits as fructose source).
6. FBOs shall ensure that suppliers of heat treated ingredients which are susceptible to acrylamide formation carry out an acrylamide risk assessment and implement the appropriate mitigation measures.
7. FBOs shall ensure that a change in products sourced from suppliers does not result in increased acrylamide levels in such cases.
8. FBOs shall consider to add organic acids to the production process or decrease the levels of pH as far as possible and reasonable in combination with other mitigation measures and taking into account that this can result in organoleptic changes (less browning, modification of taste).

Processing

FBOs shall take the following mitigation measures in the manufacture of fine bakery wares and shall ensure that the measures taken are compatible with the product characteristics and food safety requirements:

1. FBO shall apply the heat input, i.e. time and temperature combination that is the most effective to reduce acrylamide formation while achieving the targeted product characteristics.
2. FBOs shall increase the moisture content in the final product in consideration of achieving the targeted product quality, the required shelf life and food safety standards.
3. Products shall be baked to a lighter colour endpoint in the final product in consideration of achieving the targeted product quality, the required shelf life and food safety standards.
4. In developing new products, FBOs shall take into account in their risk assessment the size and surface area of a particular piece of product taking into account that small product size potentially leads to higher acrylamide levels due to heat impact.
5. As certain ingredients used in the manufacture of fine bakery wares could be heat treated several times (e.g. pre-processed cereal pieces, nuts, seeds, dried fruits, etc.), which results in the raise of acrylamide levels in final products, FBOs shall adjust product and process design accordingly to comply with the benchmark levels of acrylamide set out in Annex IV. In particular the FBOs shall not use burnt products as rework.
6. For product pre-mixes that are put on the market to be baked at home or in catering establishments, FBOs shall provide preparation instructions to their customers to ensure that the acrylamide levels in the final products are as low as reasonably achievable below the benchmark levels.

IV. BREAKFAST CEREALS

Agronomy

In case of contract farming, where agricultural products are supplied to FBOs directly by their producers, FBOs shall ensure that the following requirements to prevent elevated asparagine levels in cereals are applied:

- to follow Good Agricultural Practices on fertilisation, in particular with regard to maintaining balanced sulphur levels in the soil and to ensure a correct nitrogen application;
- to follow Good Phytosanitary Practices in order to ensure the application of good practices on crop protection measures to prevent fungal infection.

FBOs shall carry out controls to verify the effective application of the aforesaid requirements.

Recipe

1. Given that products based on maize and rice tend to have less acrylamide than those made with wheat, rye, oats and barley, FBOs shall consider using maize and rice in new product development where applicable and taking into consideration that any change will have an impact on the manufacturing process and organoleptic properties of the products.
2. FBOs shall control the addition rates at the point of addition of reducing sugars (e.g. fructose and glucose) and ingredients containing reducing sugars (e.g. honey) taking into consideration their impact on organoleptic properties and process functionalities (binding clusters for cluster formation) and which can act as precursors to acrylamide formation when added prior to heat-treatment stages.
3. FBOs shall take into account in the risk assessment the acrylamide contribution from heat-treated, dry ingredients, such as roasted and toasted nuts and oven dried fruits, and use alternative ingredients if the contribution is likely to bring the finished product above the benchmark level specified in Annex IV.
4. For heat-treated ingredients which contain 150 micrograms of acrylamide per kilogram ($\mu\text{g/kg}$) or more, FBOs shall take the following actions:
 - to establish a register of such ingredients;
 - to carry out audits of suppliers and/or analyses;
 - to ensure that no changes are made by the supplier of such ingredients that increase acrylamide levels.
5. When the cereal is in a flour dough format and the manufacturing process allows a sufficient time, temperature and moisture content for asparaginase to reduce asparagine levels, FBOs shall use asparaginase where required provided there is no adverse effect on flavour or risk of residual enzyme activity.

Processing

In the manufacture of breakfast cereals FBOs shall apply the following mitigation measures and shall ensure that the measures taken are compatible with the product characteristics and food safety requirements:

1. FBOs shall identify, by means of risk assessment, the critical heat-treatment step(s) in the manufacturing process that generate(s) acrylamide.
2. As higher heating temperatures and longer heating times generate higher acrylamide levels, FBOs shall identify an effective combination of temperature and heating times to minimise acrylamide formation without compromising the taste, texture, colour, safety and shelf-life of the product.
3. To avoid the generation of acrylamide spikes, FBOs shall control heating temperatures, times and feed-rates in order to achieve the following minimum moisture content in the final product after the final heat treatment in consideration of achieving the targeted product quality, the required shelf life and food safety standards:
 - toasted products: 1 g/100 g for extruded products, 1 g/100 g for batch cooked products, 2 g/100 g for steam rolled products;
 - direct expanded products: 0,8 g/100 g for extruded products;
 - baked products: 2 g/100 g for continuously cooked products;
 - filled products: 2 g/100 g for extruded products;
 - other drying: 1 g/100 g for batch cooked products, 0,8 g/100 g for gun puffed products.

FBOs shall measure the moisture content and express acrylamide concentration in a dry mass to eliminate the confounding effect of moisture changes.
4. Reworking product back through the process has the potential to generate higher acrylamide levels through repeated exposure to the heat-treatments steps. FBOs therefore shall assess the impact of rework on acrylamide levels and reduce or eliminate rework.
5. FBOs shall have procedures in place, such as temperature controls and monitoring, to prevent the incidence of burnt products.

V. COFFEE

Recipe

In considering coffee blend composition FBOs shall take into account in the risk assessment that products based on Robusta beans tend to have higher acrylamide levels than products based on Arabica beans.

Processing

1. FBOs shall identify the critical roast conditions to ensure minimal acrylamide formation within the target flavour profile.
2. Control of roast conditions shall be incorporated into a Pre-requisite Program (PRP) as part of Good Manufacturing Practice (GMP).
3. FBOs shall consider the use of asparaginase treatment, insofar possible and effective to reduce the presence of acrylamide.

VI. COFFEE SUBSTITUTES CONTAINING MORE THAN 50% CEREALS

Agronomy

In case of contract farming, where agricultural products are supplied to FBOs directly by their producers, FBOs shall ensure that the following requirements to prevent elevated asparagine levels in cereals are applied:

- to follow Good Agricultural Practices on fertilisation, in particular with regard to maintaining balanced sulphur levels in the soil and to ensure a correct nitrogen application;
- to follow Good Phytosanitary Practices in order to ensure the application of good practices on crop protection measures to prevent fungal infection.

FBOs shall carry out controls to verify the effective application of the aforesaid requirements.

Recipe

1. Given that products based on maize and rice tend to have less acrylamide than those made with wheat, rye, oats and barley, FBOs shall consider using maize and rice in the new product development where applicable, taking into consideration that any change will have an impact on the manufacturing process and organoleptic properties of the product.
2. FBOs shall control the addition rates at the point of addition of reducing sugars (e.g. fructose and glucose) and ingredients containing reducing sugars (e.g. honey) taking into consideration the impact on organoleptic properties and process functionalities (binding clusters) and which can act as precursors to acrylamide formation when added prior to heat-treatment stages.
3. If coffee substitutes are not made exclusively from cereals, FBOs shall use of other ingredients which result in lower levels of acrylamide after high temperature processing where applicable.

Processing

1. FBOs shall identify the critical roast conditions to ensure minimal acrylamide formation within the target flavour profile.
2. Control of roast conditions shall be incorporated into a Pre-requisite Program (PRP) as part of Good Manufacturing Practice (GMP).

VII. COFFEE SUBSTITUTES CONTAINING MORE THAN 50% CHICORY

1. FBOs shall purchase only cultivars low in asparagine and FBOs shall ensure that no late and excessive nitrogen application has taken place during the growth of chicory.

Recipe

2. If coffee substitutes are not made exclusively from chicory namely, chicory content is less than 100% and more than 50%, FBOs shall add other ingredients, such as chicory fibres, roasted cereals, as these have been shown to be effective to reduce the acrylamide content in the final product.

Processing

1. FBOs shall identify the critical roast conditions to ensure minimal acrylamide formation within the target flavour profile. Conclusions shall be documented.
2. Control of roast conditions shall be incorporated into the manufacturer's food safety management system.

VIII. BABY BISCUITS AND INFANT CEREALS⁵

In case of contract farming, where agricultural products are supplied to FBOs directly by their producers, FBOs shall ensure that the following requirements to prevent elevated asparagine levels in cereals are applied:

- to follow Good Agricultural Practices on fertilisation, in particular with regard to maintaining balanced sulphur levels in the soil and to ensure a correct nitrogen application;
- to follow Good Phytosanitary Practices in order to ensure the application of good practices on crop protection measures to prevent fungal infection.

FBOs shall carry out controls to verify the effective application of the aforesaid requirements.

Product Design, Processing and Heating

1. FBOs shall use asparaginase to reduce the levels of asparagine in the flour raw material insofar possible. FBOs that cannot use asparaginase due to, for example the processing requirements or product design, shall use flour raw material low in acrylamide precursors, such as fructose and glucose and asparagine.
2. FBOs shall make an assessment during recipe development that provides information on reducing sugars and asparagine, and includes options on achieving low reducing sugars in the final recipe. This need for this assessment will be dependent on use of asparaginase in the recipe.
3. FBOs shall ensure that heat treated ingredients which are susceptible to acrylamide formation are obtained from suppliers that are able to demonstrate that they have taken the appropriate mitigation measures to reduce the presence of acrylamide in those ingredients.
4. FBOs shall have a change control procedure in place to ensure that they do not make any supplier changes that increase acrylamide.
5. If the use of heat-treated raw materials and ingredients results in that in the final product the acrylamide benchmark level specified in Annex IV is exceeded, FBOs shall review the use of those products in view of achieving levels of acrylamide as low as reasonably achievable below the benchmark level set out in Annex IV.

⁵

As defined in 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).

Recipe

1. Given that products based on maize and rice tend have less acrylamide than those made with wheat, rye, oats and barley, FBOs shall consider using maize and rice in new product development where applicable taking into consideration that any change will have an impact on the manufacturing process and organoleptic properties of the product.
2. FBOs shall take into account, in particular in their risk assessment, that products based on wholegrain cereals and/or with high levels of cereal bran have higher levels of acrylamide.
3. FBOs shall control the addition rates at the point of addition of reducing sugars (e.g. fructose and glucose) and ingredients containing reducing sugars (e.g. honey) taking into consideration the impact on organoleptic properties and process functionalities (binding clusters) and which can act as precursors to acrylamide formation when added prior to heat-treatment stages.
4. FBO shall determine the acrylamide contribution from heat-treated and dry ingredients, such as roasted and toasted nuts and oven dried fruits, and use alternative ingredients if the use of those ingredients brings the finished product above the benchmark level specified in Annex IV.

Processing

1. FBOs shall identify, by means of risk assessment, the critical heat-treatment step(s) in the manufacturing process that generate(s) acrylamide.
2. FBOs shall measure the moisture content and express acrylamide concentration in a dry mass to eliminate the confounding effect of moisture changes.
3. FBOs shall identify and apply an effective combination of temperature and heating times to minimise acrylamide formation without compromising the taste, texture, colour, safety and shelf-life of the product.
4. FBOs shall control heating temperatures, times and feed-rates. Feed-rate and temperature control measurement systems should be calibrated regularly and these operating conditions controlled within set limits. These tasks shall be incorporated into the HACCP procedures.
5. Monitoring and controlling product moisture content after the critical heat-treatment steps has proved to be effective in controlling acrylamide levels in some processes and therefore, in these circumstances, this process can be an adequate alternative to controlling heating temperatures and times, hence shall be employed.

IX. BABY JAR FOODS (LOW-ACID AND PRUNE-BASED FOODS)⁶

1. For the production of baby jar foods, FBOs shall choose raw materials with low acrylamide precursor content, e.g. reducing sugars such as fructose and glucose and asparagine.
2. In case of contract farming, where agricultural products are supplied to FBOs directly by their producers, FBOs shall ensure that the following requirements to prevent elevated asparagine levels in cereals are applied:
 - to follow Good Agricultural Practices on fertilisation, in particular with regard to maintaining balanced sulphur levels in the soil and to ensure a correct nitrogen application;
 - to follow Good Phytosanitary Practices in order to ensure the application of good practices on crop protection measures to prevent fungal infection.

FBOs shall carry out controls to verify the effective application of the aforesaid requirements.

3. In prune purée purchase contracts FBOs shall include requirements which ensure that heat treatment regimes in the prune purée manufacturing process are applied that aim to reduce the occurrence of acrylamide in that product.
4. FBOs shall ensure that heat treated ingredients which are susceptible to acrylamide formation are obtained from suppliers that are able to demonstrate that they have taken the mitigation measures to reduce the presence of acrylamide in those ingredients.
5. If the use of heat- treated raw materials and ingredients results in that in the final product the benchmark level of acrylamide specified in Annex IV is exceeded, FBOs shall review the use of those materials and ingredients in view of achieving levels of acrylamide as low as reasonably achievable below the benchmark level set out in Annex IV.

Recipe

1. FBOs shall take into account in the risk assessment of acrylamide in the foodstuffs concerned that products based on wholegrain cereals and/or with high levels of cereal bran have higher levels of acrylamide.
2. FBOs shall choose varieties of sweet potatoes and prunes which are as low as possible in acrylamide precursors, such as reducing sugars (e.g. fructose and glucose) and asparagine.
3. FBOs shall control the addition rates at the point of addition of reducing sugars (e.g. fructose and glucose) and ingredients containing reducing sugars (e.g. honey) added for organoleptic reasons and process functionalities (binding clusters) and which can act as precursors to acrylamide formation when added prior to heat-treatment stages.

⁶

As defined in 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).

Processing

1. FBOs shall identify the key heat-treatment step(s) in the process that generate(s) the most acrylamide in order to focus further acrylamide reduction/control efforts most effectively. This has to be achieved either via a risk assessment or by directly measuring the acrylamide levels in the product before and after each heat-treatment step.
2. To avoid the generation of acrylamide spikes, FBO shall control heating temperatures, times and feed-rates. Feed-rate and temperature control measurement systems should be calibrated regularly and these operating conditions controlled within set limits. These tasks shall be incorporated into the HACCP procedures.
3. FBOs shall ensure that the lowering of thermal input to reduce acrylamide in low acid and prune based foods do not affect microbiological safety of the foodstuffs concerned.

X. BREAD

Agronomy

In case of contract farming, where agricultural products are supplied to FBOs directly by their producers, FBOs shall ensure that the following requirements to prevent elevated asparagine levels in cereals are applied:

- to follow Good Agricultural Practices on fertilisation, in particular with regard to maintaining balanced sulphur levels in the soil and to ensure a correct nitrogen application;
- to follow Good Phytosanitary Practices in order to ensure the application of good practices on crop protection measures to prevent fungal infection.

FBOs shall carry out controls to verify the effective application of the aforesaid requirements.

Product design, processing and heating

1. FBOs shall ensure that bread is baked to a lighter colour endpoint to reduce acrylamide formation taking into account individual product design and technical possibilities.
2. FBOs shall extend the yeast fermentation time taking into account the product design and the technical possibilities.
3. FBOs shall lower thermal input by optimising baking temperature and time insofar possible.
4. FBOs shall provide baking instructions for bread that is to be finished at home, in bake-off areas, retail shops or in catering establishments.
5. FBOs shall substitute ingredients that have the potential to raise acrylamide levels in the final product where this is compatible with product design and technical possibilities, that includes for instance the use of nuts and seeds roasted at lower rather than higher temperatures.
6. FBOs shall replace fructose with glucose particularly in recipes containing ammonium bicarbonate (E503) where the product design allows and insofar

possible. That includes, for instance, replacing invert sugar syrup and honey, which contain higher levels of fructose, with glucose syrup.

7. In products with low moisture content, FBOs shall use asparaginase to reduce asparagine insofar possible and taking into account product recipe, ingredients, moisture content and process.

ANNEX II

PART A

MITIGATION MEASURES TO BE APPLIED BY FOOD BUSINESS OPERATORS (FBOs) REFERRED TO IN ARTICLE 2(2)

1. FBOs producing potato products shall apply the following mitigation measures:
 - French fries and other cut (deep fried) potato products:
 - Potato varieties with lower sugar content shall be used, when available and insofar as compatible with the desired food product to be obtained. In this respect the provider shall be consulted for best suited potato varieties.
 - Potatoes shall be stored at a temperature higher than 6°C.
 - Before the frying process:

Except for frozen potato products for which cooking instructions shall be followed, one of the following measures shall be taken with raw French fries to reduce the sugar content, where possible and insofar as compatible with the desired food product to be obtained:

 - Washing and soaking preferably for 30 minutes up to 2 hours in cold water. Rinse the strips in clean water before frying.
 - Soaking for a few minutes in warm water. Rinse the strips in clean water before frying.
 - Blanching of potatoes results in lower levels of acrylamide and therefore where possible, it is appropriate to blanch potatoes.
 - When frying French fries or other potato products:
 - Frying oils and fats shall be used which allows to fry quicker and/or at lower temperatures. Cooking oil suppliers shall be consulted for the best suited oils and fats.
 - Frying temperatures shall be below 175°C and in any case as low as possible taking into account the food safety requirements.
 - Frying oils and fats quality shall be maintained by skimming frequently to remove fines and crumbs.

For the cooking of French fries, it is appropriate that the FBOs make use of available colour guides providing guidance on the optimal combination of colour and low levels of acrylamide.

It is appropriate that a colour guide providing guidance on the optimal combination of colour and low levels of acrylamide is visibly displayed at the premises to the staff preparing the food.

2. FBOs producing bread and fine bakery wares shall use the following mitigation measures in the baking process:
 - Insofar possible and compatible with the production process and hygiene requirements:
 - the extension of yeast fermentation time;

- the moisture content of the dough for the production of a product with low moisture content, shall be optimised;
- the lowering of oven temperature and the extension cooking time.

Products shall be baked to a lighter colour endpoint and dark roasting of crust shall be avoided in case the dark colour of the crust is the result of the strong roasting and not related to the specific composition or nature of the bread resulting in a dark crust.

3. When preparing sandwiches, the FBOs shall ensure that sandwiches are toasted to the optimal colour. It is appropriate that colour guides developed for specific product types, when available, providing guidance on the optimal combination of colour and low levels of acrylamide are used when producing these specific products. When using pre-packed bread or bakery products which are to be finished, cooking instructions are followed.

The abovementioned colour guide providing guidance on the optimal combination of colour and low levels of acrylamide shall be visibly displayed at the premises to the staff preparing the specific food.

PART B

MITIGATION MEASURES TO BE APPLIED BY FOOD BUSINESS OPERATORS REFERRED TO IN ARTICLE 2(3) IN ADDITION TO THE MITIGATION MEASURES REFERRED TO IN PART A

1. **General requirement**

FBOs shall accept products referred to in Article 1(2) of this Regulation only from FBOs that have implemented all mitigation measures set out in Annex I to this Regulation.

2. **French fries and other cut (deep fried) potato products**

FBOs shall

- follow the instructions on storage of provided by the FBOs or the suppliers or provided for in the relevant mitigation measures in Annex I;
- work with Standard Operational Procedures and calibrated fryers equipped with computerised timers and programmed to standard settings (time-temperature);
- monitor the level of acrylamide in finished products to verify that the mitigation measures are effective in keeping acrylamide levels below the benchmark level.

3. **Bakery products**

FBOs shall:

- monitor the level of acrylamide in finished products to verify that the mitigation measures are effective in keeping acrylamide levels below the benchmark level.

4. Coffee

FBOs shall:

- ensure that the level of acrylamide in supplied coffee is lower than the benchmark level specified in Annex IV taking into account however that this may not be possible for all coffee types depending on blend and roast characteristics. In these cases a justification is provided by the supplier.

ANNEX III

SAMPLING AND ANALYSIS REQUIREMENTS FOR THE MONITORING REFERRED TO IN ARTICLE 4

(I) Sampling

- (1) The sample shall be representative for the sampled batch.
- (2) 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.
- (3) 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 be risk-based where further mitigation measures are feasible.

(II) Analysis

- (1) FBOs shall provide sufficient data to enable an assessment of the level of acrylamide and of the likelihood that the product type might exceed the benchmark level.
- (2) The sample shall be analysed in a laboratory that participates in appropriate proficiency testing schemes (which comply with the ‘International Harmonised Protocol for the Proficiency Testing of (Chemical) Analytical Laboratories’⁷ developed under the auspices of IUPAC/ISO/AOAC) and uses approved analytical methods for detection and quantification. Laboratories shall be able to demonstrate that they have internal quality control procedures in place. Examples of these are the ‘ISO/ AOAC/IUPAC Guidelines on Internal Quality Control in Analytical Chemistry Laboratories’⁸.

Wherever possible the trueness of analysis shall be estimated by including suitable certified reference materials in the analysis.

- (3) The method of analysis used for the analysis of acrylamide must comply with the following performance criteria

Parameter	Criterion
Applicability	Foods specified in this Regulation
Specificity	Free from matrix or spectral interferences
Field blanks	Less than Limit of Detection (LOD)
Repeatability (RSD _r)	0.66 times RSD _R as derived from (modified) Horwitz equation
Reproducibility (RSD _R)	as derived from (modified) Horwitz equation
Recovery	75-110 %

⁷ M. Thompson et al, Pure and Applied Chemistry, 2006, 78, pp. 145-196.

⁸ Edited by M. Thompson and R. Wood, Pure and Applied Chemistry, 1995, 67, pp. 649-666.

Limit of Detection (LOD)	Three tenths of LOQ
Limit of Quantification (LOQ)	For benchmark level < 125 µg/kg: ≤ two fifths of the benchmark level (however not required to be lower than 20 µg/kg) For benchmark level ≥ 125 µg/kg: ≤ 50 µg/kg

- (4) Analysis of acrylamide can be replaced by measurement of product attributes (e.g. colour) or process parameters provided that a statistical correlation can be demonstrated between the product attributes or process parameters and the acrylamide level.

(III) Frequency of sampling

- (1) FBOs shall, undertake sampling and analysis at least annually for products that have a known and well-controlled acrylamide level. FBOs shall carry out higher frequency sampling and analysis of products having the potential to exceed the benchmark level and shall be risk-based where further mitigation measures are feasible.
- (2) Based on this assessment referred to in point II(1) of this Annex, the FBOs shall specify appropriate frequencies for analysis for each product type. The assessment shall be repeated if a product or process is modified in a way that could lead to a change in the acrylamide level in the final product.

(IV) Mitigation

If the analytical result, corrected for recovery but not taking into account the measurement uncertainty, indicates that a product has exceeded the benchmark level, or contains acrylamide at a level higher than anticipated (taking into account previous analyses, but lower than the benchmark level), then the 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.

(V) Information to competent authorities

FBOs 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.

ANNEX IV

BENCHMARK LEVELS REFERRED TO IN ARTICLE 1(1)

Benchmark levels for the presence of acrylamide in foodstuffs referred to in Article 1(1) are as follows:

Food	Benchmark level [µg/kg]
French fries (ready-to-eat)	500
Potato crisps from fresh potatoes and from potato dough Potato-based crackers Other potato products from potato dough	750
Soft bread (a) Wheat based bread (b) Soft bread other than wheat based bread	50 100
Breakfast cereals (excl. porridge) - bran products and whole grain cereals, gun puffed grain - wheat and rye based products (*) - maize, oat, spelt, barley and rice based products (*) (*) non-whole grain and/or non-bran based cereals. The cereal present in the largest quantity determines the category.	300 300 150

Biscuits and wafers	350
Crackers with the exception of potato based crackers	400
Crispbread	350
Ginger bread	800
Products similar to the other products in this category	300
Roast coffee	400
Instant (soluble) coffee	850
Coffee substitutes	
(a) coffee substitutes exclusively from cereals	500
(b) coffee substitutes from a mixture of cereals and cichory	(*)
(c) coffee substitutes exclusively from cichory	4000
(*) the benchmark level to be applied to coffee substitutes from a mixture of cereals and cichory takes into account the relative proportion of these ingredients in the final product.	
Baby foods, processed cereal based foods for infants and young children excluding biscuits and rusks ⁹ ,	40
Biscuits and rusks for infants and young children ¹⁰	150

⁹ As defined in 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).

¹⁰ As defined in Regulation (EU) No 609/2013 referred to above.