



EUROPEAN  
COMMISSION

Brussels, **XXX**  
SANTE/11059/2016 -revision9  
**[...]**(2016) **XXX** draft

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

**of **XXX****

**on the application of control and mitigation measures to reduce the presence of  
acrylamide in food**

(Text with EEA relevance)

**WORKING DOCUMENT – DOES NOT  
NECESSARILY REPRESENT THE VIEWS OF  
THE EUROPEAN COMMISSION SERVICES**

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

**of XXX**

**on the application of control and mitigation measures to reduce the presence of  
acrylamide in food**

(Text with EEA relevance)

<p><b>WORKING DOCUMENT – DOES NOT NECESSARILY REPRESENT THE VIEWS OF THE EUROPEAN COMMISSION SERVICES</b></p>
---

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs<sup>1</sup>, and in particular Article 4 (4) thereof,

Whereas:

- (1) Regulation (EC) No 852/2004 aims to ensure a high level of consumer protection with regard to food safety. It defines “food hygiene” as a set of measures and conditions necessary to control hazards and to ensure fitness for human consumption of a foodstuff taking into account its intended use. Food safety hazards occur when food is exposed to hazardous agents which result in contamination of that food. Food hazards may be biological, chemical or physical.
- (2) Acrylamide is a contaminant as defined in Council Regulation (EEC) No 315/93<sup>2</sup> and as such, it is a chemical hazard in the food chain.
- (3) Acrylamide is a low molecular weight, highly water soluble, organic compound which forms from the naturally occurring constituents asparagine and sugars in certain foods when prepared at temperatures typically higher than 120°C and low moisture. It mainly forms in baked or fried carbohydrate-rich foods where raw materials contain its precursors, such as French fries, potato crisps, breads, biscuits and coffee.
- (4) As the acrylamide levels in some foodstuffs appear to be significantly higher than the levels in comparable products of the same product category, a Commission Recommendation 2013/647/EU<sup>3</sup> invited Member States' competent authorities to carry out investigations in the production and processing methods used by food business operators if the acrylamide level found in a specific foodstuff exceeded the indicative values set out in the Annex to that Recommendation.

---

<sup>1</sup> OJ L 139, 30.4.2004, p. 1

<sup>2</sup> Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food (OJ L 37, 13.2.1993, p. 1).

<sup>3</sup> Commission Recommendation 2013/647/EU of 8 November 2013 on investigations into the levels of acrylamide in food (OJ L 301, 12.11.2013, p. 15).

- (5) In 2015 the Scientific Panel on Contaminants in the Food Chain (CONTAM) of the European Food Safety Authority ('the Authority') adopted an opinion on acrylamide in food<sup>4</sup>. Based on animal studies, EFSA confirms previous evaluations that acrylamide in food potentially increases the risk of developing cancer for consumers in all age groups. Since acrylamide is present in a wide range of everyday foods, this concern applies to all consumers but children are the most exposed age group on a body weight basis. Possible harmful effects of acrylamide on the nervous system, pre- and post-natal development and male reproduction were not considered to be a concern, based on current levels of dietary exposure. It was concluded that although the available human studies have not demonstrated that acrylamide is a human carcinogen, the current levels of dietary exposure to acrylamide across age groups indicate a concern with respect to carcinogenic effects"
- (6) Given the Authority's conclusions with respect to carcinogenic effects of acrylamide and that there is no consistent and mandatory measures to be applied by food businesses to lower levels of acrylamide, it is necessary to ensure food safety and to reduce the presence of acrylamide in foodstuffs where raw materials contain its precursors by laying down appropriate mitigation measures. The safety of foodstuffs as regards acrylamide is mainly ensured by a preventive approach, such as implementation of good hygiene practice and application of procedures based on hazard analysis and critical control point (HACCP) principles.
- (7) According to Article 4 of Regulation (EC) No 853/2004, food business operators are to follow the procedures necessary to meet targets set to achieve the objectives of that Regulation and to employ sampling and analysis as appropriate to maintain their own performance. In that respect, the setting of objectives, such as benchmark levels, may guide the implementation of hygiene rules while ensuring the reduction of the level of exposure to certain hazards. Mitigation measures should be applied to reduce the presence of acrylamide in food and the effectiveness of the mitigation measures to reduce the acrylamide content should be verified through sampling and analysis demonstrating that the levels of acrylamide are below established 'benchmark levels'.
- (8) It is therefore appropriate to establish mitigation measures which identify food processing steps susceptible to the formation of acrylamide in baked, fried carbohydrate-rich and roasted foods and set out activities to reduce the levels of acrylamide in those foodstuffs.
- (9) The mitigation measures set out in this Regulation are based on current scientific and technical knowledge, which have proven to result in lower levels of acrylamide without adversely affecting the quality and microbial safety of the product. These mitigation measures have been established following extensive consultation of organisations representing affected food business operators and consumers and experts from competent authorities of Member States.
- (10) Benchmark levels set for acrylamide in this Regulation are established on the basis of what is achievable by applying mitigation measures. The benchmark levels have been determined taking into account the most recent occurrence data from the Authority's database and whereby it is assumed that within a food category, the level of acrylamide in 10 to 15 % of the production with the highest levels can be lowered by applying good practices. They are to be regularly reviewed by the Commission with

---

4

The EFSA Journal 2015;13(6):4104.

the aim to set lower levels, reflecting the continuous reduction of the presence of acrylamide in food.

- (11) Food business operators, who produce ready-to-eat food and directly supply it to the final consumer and/or to the local retail establishment directly supplying the final consumer are typically small scale operators and therefore control and mitigation measures to be taken by such business operators for reduction of the acrylamide presence in foodstuffs are adapted to the nature of their operation. However, food business operators who produce ready-to-eat food and directly supply it to the final consumer in undertakings which belong to food businesses which operate multiple such undertakings and where products are supplied in a centralized manner should apply additional mitigation measures practicable for larger-scale businesses as these additional mitigation measures further reduce the presence of acrylamide in food and are feasible to be applied by such undertakings.
- (12) The effectiveness of the mitigation measures to reduce the acrylamide content is to be verified through sampling and analysis. It is appropriate to determine requirements for the sampling and analysis that has to be performed by the food business operator, as regards sampling, analytical requirements and frequency of sampling to ensure that the obtained analytical results are representative for their production.
- (13) Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004<sup>5</sup> requires the Member States to regularly perform official controls to ensure compliance with feed and food law.
- (14) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

### *Article 1*

#### Scope

1. Without prejudice to the applicable provisions of the Union law in food area, food business operators which produce and place on the market foodstuffs listed in paragraph 2 shall ensure that as a result of the application of mitigation measures set out in Annexes I and II, the levels of acrylamide referred to as benchmark levels set out in Annex IV are not exceeded.
2. Foodstuffs referred to in paragraph 1 are as follows:
  - a) French fries, other cut (deep fried) products and sliced potato crisps from fresh potatoes;
  - b) Potato crisps, snacks, crackers and other potato products from potato dough;
  - c) Bread and bread products;
  - d) Breakfast cereals (excluding porridge);

---

<sup>5</sup> Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (OJ L 165, 30.4.2004, p. 1).

- e) Fine bakery wares: [] 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);.
- f) Coffee:
  - i) Roast coffee
  - ii) Instant (soluble) coffee;
- g) Coffee substitutes:
  - i) coffee substitutes with cereal content of more than 50%
  - ii) coffee substitutes with cereal content less than 50%;
- h) Baby foods, processed cereal based foods for infants and young children as defined in Regulation (EU) No 609/2013 of the European Parliament and of the Council<sup>6</sup>.

## *Article 2*

### *Mitigation measures*

1. Food business operators, which produce and place on the market foodstuffs listed in Article 1(2) shall apply mandatory mitigation measures provided for in Annex I.
2. By way of derogation from paragraph 1, food business operators, which produce ready-to-eat foodstuffs listed in Article 1(2) and directly supply it to the final consumer and/or to the local retail establishment directly supplying the final consumer shall apply mitigation measures provided for in Part A of Annex II.
3. Food business operators referred to in paragraph 2 who produce ready-to-eat food and directly supply it to the final consumer in undertakings which belong to food businesses which operate multiple such undertakings shall apply additional mitigation measures set out in Part B of Annex II.
4. Food business operators shall review mitigation measures applied at least annually and adjust processes and controls as appropriate, taking into account all relevant factors, in particular the safety of foodstuffs.

## *Article 3*

### *Definitions*

For the purposes of this Regulation, the definitions laid down in Articles 2 and 3 of Regulation (EC) No 178/2002 shall apply.

---

<sup>6</sup> 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 L181, 29.6.2013, p. 35).

*Article 4*  
*Own checks and monitoring*

1. Food business operators referred to in Article 2(1), with the exception of food business operators referred to in Article 2(2), shall establish a programme for their own checks and monitoring of the levels of acrylamide in the foodstuffs listed in Article 1(2).
2. Food business operators referred to in Article 2(1), with the exception of food business operators referred to in Article 2(2), shall record mitigation measures referred to in Annexes I and II which are applied and any changes thereof. In respect of those mitigation measures, food business operators shall justify their decisions taken regarding the application.
3. Food business operators referred to in Article 2(1), with the exception of food business operators referred to in Article 2(2), 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 record the results of the monitoring programme.
4. If the control results indicate that the benchmark levels of acrylamide set out in Annex IV to this Regulation are exceeded, food business operators referred to in Article 2(1), with the exception of food business operators referred to in Article 2(2), shall apply without delay additional mitigation measures to ensure that further production does not exceed the benchmark level.

*Article 5*  
*Official controls*

The sampling and analysis performed by the Member States in the context of official controls to verify the compliance with this Regulation shall be carried out in accordance with the provisions provided for in Commission Regulation (EC) No 333/2007<sup>7</sup>.

*Article 6*  
*Review of the levels of acrylamide*

The benchmark levels of acrylamide presence in foodstuffs set out in Annex IV shall be reviewed by the Commission every three years and the first time within three years after the entry into application of this Regulation.

*Article 7*  
*Entry into force and application*

---

<sup>7</sup> Commission Regulation (EC) No 333/2007 of 28 March 2007 laying down the methods of sampling and analysis for the control of the levels of trace elements and processing contaminants in foodstuffs (OJ L 88, 29.3.2007, p. 29).

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

It shall apply from [4 months after the entry into force].

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

Done at Brussels,

*For the Commission*  
*The President*  
*Jean-Claude JUNCKER*