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COMMISSION REGULATION (EU) …/…

of XXX

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

(Text with EEA relevance)

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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[1], 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[2] 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 forms mainly in baked or fried carbohydrate-rich foods where raw materials contain its precursors, such as cereals, potatoes and coffee beans.

(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[3] 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.

(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[4]. Based on animal studies, the Authority confirms previous evaluations that acrylamide in food potentially increases the risk of developing cancer for consumers in

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1 OJ L 139, 30.4.2004, p. 1

2 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).

3 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).

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

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. The current levels of dietary exposure to acrylamide across age groups indicate a concern with respect to its carcinogenic effects.

(6) Given the Authority's conclusions with respect to carcinogenic effects of acrylamide and in the absence of any consistent and mandatory measures to be applied by food businesses in order 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 levels of acrylamide can be lowered by mitigation approach, such as implementation of good hygiene practice and application of procedures based on hazard analysis and critical control point (HACCP) principles.

(7) In accordance with Article 4 of Regulation (EC) No 852/2004, 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 targets, 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 would lower the presence of acrylamide in food. In order to check the compliance with the benchmark levels the effectiveness of mitigation measures should be verified through sampling and analysis.

(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 and they have proven to result in lower levels of acrylamide without adversely affecting the quality and microbial safety of the product. Those mitigation measures have been established following extensive consultation of organisations representing affected food business operators, consumers and experts from competent authorities of Member States.

(10) Benchmark levels are performance indicators to be used to verify the effectiveness of the mitigation measures and are based on experience and occurrence for broad food categories. They should be established at a level as low as reasonably achievable with the application of all mitigation measures. The benchmark levels should be determined taking into account the most recent occurrence data from the Authority's database, whereby it is assumed that within a broad food category, the level of acrylamide in 10 to 15 % of the production with the highest levels can usually be lowered by applying good practices. It is acknowledged that the specified food categories are in certain cases broad and that for specific foods within such a broad food category there may 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 mitigation measures. In such situations, the food business operator should be able to show the evidence that he applied the relevant mitigation measures.

(11) The benchmark levels should be regularly reviewed by the Commission with the aim to set lower levels, reflecting the continuous reduction of the presence of acrylamide in food.

(12) Food business operators, producing foodstuffs within the scope of this Regulation and which perform retail activities and/or directly supply only local retail establishments are typically small scale operators. Therefore, mitigation measures are adapted to the nature of their operation. However, food business operators which are part of, or franchises of, a larger, interconnected operation and that are centrally supplied should apply additional mitigation measures practicable for larger-scale businesses as those measures further reduce the presence of acrylamide in food and are feasible to be applied by such undertakings.

(13) The effectiveness of the mitigation measures to reduce the acrylamide content should 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 operators. As regards sampling, analytical requirements and frequency of sampling should be established in order to ensure that the obtained analytical results are representative for their production. Food business operators, producing foodstuffs within the scope of this Regulation and which perform retail activities and/or directly supply only local retail establishments are exempted from the obligation to sample and analyse their production for the presence of acrylamide as such a requirement would put a disproportionate burden on their business.

(14) In addition to sampling and analysis by the business operators, Regulation (EC) No 882/2004[5] requires the Member States to regularly perform official controls to ensure compliance with feed and food law. The sampling and analysis performed by the Member States in the context of official controls should comply with the sampling procedures and analytical criteria established in application of Regulation (EC) No 882/2004.

(15) Complementary to the measures provided for in this Regulation, the setting of maximum levels for acrylamide in certain foods should be considered in accordance with Council Regulation (EEC) No 315/93 following the entry into force of this Regulation.

(16) The implementation of the mitigation measures by food business operators might involve changes to their current production process therefore, it is appropriate to provide for a transitional period before the measures provided for in this Regulation apply.

(17) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

[5] 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).

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/or place on the market foodstuffs listed in paragraph 2 shall in accordance with Article 2 apply the mitigation measures set out in Annexes I and II, in view of achieving the benchmark levels set out in Annex IV.

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;

   (d) breakfast cereals (excluding porridge);

   (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);.

   (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 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[6].

Article 2
Mitigation measures

1. Food business operators, which produce and/or place on the market foodstuffs listed in Article 1(2) shall apply mitigation measures provided for in Annex I.

2. By way of derogation from paragraph 1, food business operators producing foodstuffs listed in Article 1(2), which perform retail activities, and/or directly supply only local retail establishments shall apply mitigation measures provided for in Part A of Annex II.

[6] 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).

3. Food business operators referred to in paragraph 2 which are part of, or franchises of, a larger, interconnected operation and that are centrally supplied shall apply additional mitigation measures set out in Part B of Annex II.

4. When the benchmark levels are exceeded, food business operators shall review the mitigation measures applied and adjust processes and controls. Food business operators shall take into account the safety of foodstuffs, specific production and geographic conditions or product characteristics in view of achieving the benchmark levels set out in Annex IV.

Article 3
Definitions

For the purposes of this Regulation, the following definitions shall apply:

1. the definitions of 'food', 'food business operator', 'retail' 'placing on the market' and 'final consumer' laid down in Articles 2 and 3 of Regulation (EC) No 178/2002[7].

2. 'benchmark levels' means performance indicators used to verify the effectiveness of the mitigation measures and are based on experience and occurrence for broad food categories.

Article 4
Sampling and analysis

1. Food business operators referred to in Article 2(1) shall establish a programme for their own sampling and analysis of the levels of acrylamide in the foodstuffs listed in Article 1(2).

2. Food business operators referred to in Article 2(1) shall keep a record of the applied mitigation measures set out in Annex I.

3. 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.

4. Food business operators 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.

5. If the sampling and analysis results indicate that the benchmark levels of acrylamide set out in Annex IV to this Regulation are not achieved, food business operators referred to in Article 2(1) and 2(3) shall review without delay the mitigation measures in accordance with Article 2(4).

6. By way of derogation, this Article does not apply to food business operators referred to in Article 2(2). Those food business operators shall be able to provide evidence of the application of mitigation measures set out in part A of Annex II.

[7] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1)

Article 5
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.

The review of the benchmark levels shall be based on the occurrence data of acrylamide from the Authority's database, related to the review period and provided to the Authority's database by competent authorities and food business operators.

Article 6
Entry into force and application

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