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COMMISSION REGULATION (EU) …/…

of XXX

on the application of codes of good practice 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

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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) The Scientific Panel on Contaminants in the Food Chain (CONTAM) of the European Food Safety Authority (EFSA) adopted an opinion on acrylamide in food[2]. The CONTAM Panel concluded that although the available human studies have not demonstrated that acrylamide is a human carcinogen, the Margin of Exposure (MOEs) based on the current levels of dietary exposure to acrylamide across surveys and age groups indicate a concern with respect to carcinogenic effects.

(2) It is therefore appropriate to reduce the presence of acrylamide as much as possible by applying measures to prevent and reduce formation of acrylamide in specific manufacturing practices. These measures are contained in Codes of Practice which have been developed by the relevant sector organisations. These Codes of Practice have been scrutinised and commented by the Commission services and competent authorities and updated according by the sector organisations. The Codes of practice have been endorsed by the Standing Committee on Plants, Animals, Food and Feed. Codes of Practice have been developed for potato based products, cereal based products, coffee and coffee substitutes and baby food and for plant bakery products. Specific codes of practices have been elaborated for food business operators who place on the market directly to the consumer ready-to-eat food.

(3) Given the human health concerns related to the presence of acrylamide in food, it is appropriate to make the application of the Codes of Practice mandatory.

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1 OJ L 139, 30.4.2004, p. 1

2 EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), 2015. Scientific Opinion on acrylamide in food. EFSA Journal 2015;13(6):4104, 321 pp. doi:10.2903/j.efsa.2015.4104 Available online: www.efsa.europa.eu/efsajournal

(4) Food business operators should establish an ongoing monitoring programme as part of their established Food Safety Management Systems to analyse their food products for the presence of acrylamide. Data from the programme should be used to confirm that, via the application of the obligatory requirements within the Code of Practice, they are successfully managing acrylamide levels. Specific levels are set to be used by food business operators as benchmark to verify the effectiveness of their controls. To ensure that the analytical results are reliable, the analysis should be performed in compliance with the analytical requirements provided for in Regulation (EC) 333/2007.

(5) The successful application of the Codes of Practice should result in lower levels of acrylamide. Therefore the levels to be used as benchmark should be regularly reviewed based on the most recent occurrence data.

(6) The Codes of practice should also be regularly reviewed to take into account the developments in new mitigation measures to further reduce the presence of acrylamide in food.

(7) To ensure that the Codes of Practice are applied by the food business operators and that food business operators fulfil their obligations to check the effectiveness of the mitigation measures to reduce the presence of acrylamide in food by taking sufficient samples and analyse for the presence of acrylamide, the Member States should put in place effective controls. The sampling and analysis should be performed in accordance with the provisions provided for in Commission Regulation (EC) No 333/2007.

(8) It is important for public health that the measures provided for in this Regulation result in an effective reduction of the presence of acrylamide in food. It is therefore important that a regular exchange of experiences with the implementation of the measures provided for in this Regulation is foreseen and that a temporal trend analysis of the levels of acrylamide in foodstuffs across the European Union is performed every three years on the basis of the data submitted to EFSA by the Member States as an instrument to verify the effectiveness of the measures to reduce acrylamide in food.

(9) 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

Food business operators shall apply the Codes of Practice referred to Annex I of this Regulation. Food business operators shall also comply with the requirements related to the application of the Codes of practice, provided for in Annex II.

Article 2

The food business operators, referred to in Annex II, point 1, shall maintain records of testing of their products to verify that, via the application of the mandatory requirements within the Code of Practice, levels of acrylamide are reached as low as reasonably achievable. The values included in Annex III are to be used as benchmark to verify the effectiveness of the application of the Codes of Practice.

Article 3

The values provided for in Annex III shall be regularly reviewed in view of a further reduction of the levels of acrylamide in food on the basis of most recent occurrence data. The Codes of Practice shall also be updated as required in the light of new developments.

Article 4

Member States shall perform regular controls on the presence of acrylamide in food on the market and on the application of the relevant Code of Practice by the food business operators. At these controls, food business operators shall provide the evidence of applying the Code of Practice, provide the analytical results of their monitoring of the effectiveness of the mitigation measures and the evidence of taking remediation measures in case indicative levels were exceeded.

Article 5

The sampling and analysis performed by the Member States for the control on the presence of acrylamide shall be performed in accordance with the provisions provided for in Commission Regulation (EC) No 333/2007[3].

Food business operators shall ensure that their sampling is representative for their production and that the analysis is performed in compliance with the analytical requirements provided for in Regulation (EC) 333/2007.

Article 6

The outcome of the controls referred to in Article 4 shall be discussed regularly with the competent authorities of the Member States, for the first time one year after the entry into application of this Regulation. If the application of the Code of Practice in a certain sector is not sufficient, additional risk management measures, such as the setting of maximum levels for acrylamide in application of Council Regulation (EEC) No 315/93[4], shall be taken to ensure that the levels of acrylamide in products from that sector are reduced.

Member States shall provide the analytical results from the controls referred to in Article 4 on a regular basis to EFSA in the EFSA data submission format in line with the requirements of EFSA's Guidance on Standard Sample Description (SSD) for Food and Feed[5] and the additional EFSA's specific reporting requirement.

EFSA shall perform three years after the entry into application of the Regulation a temporal trend analysis of the levels of acrylamide in foodstuffs across the European Union on the basis of the data submitted to EFSA by the Member States to verify the effectiveness of the measures to reduce acrylamide in food.

Article 7

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3 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).

4 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)

5 http://www.efsa.europa.eu/en/data/toolbox

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 as 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