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

**of **XXX****

**amending Annex III to Regulation (EC) No 853/2004 of the European Parliament and of the Council as regards specific hygiene requirements for insects intended for human consumption**

(Text with EEA relevance)

*This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.*

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

of **XXX**

## **amending Annex III to Regulation (EC) No 853/2004 of the European Parliament and of the Council as regards specific hygiene requirements for insects intended for human consumption**

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin<sup>1</sup> and in particular Article 10(1) thereof,

Whereas:

- (1) Regulation (EC) No 853/2004 lays down specific rules on the hygiene of food of animal origin for food business operators. In particular, food business operators are to ensure compliance with specific requirements for food of animal origin set out in Annex III to that Regulation.
- (2) Insects intended for human consumption are increasingly produced in or exported to the Union, as they are used as a suitable alternative to mainstream food of animal origin.
- (3) On 5 October 2015, the European Food Safety Authority (EFSA) adopted a scientific opinion providing a risk profile related to production and consumption of insects as food and feed<sup>2</sup> and concluded that for both biological and chemical hazards, the specific production methods, the substrate used, the stage of harvest, the insect species, as well as the methods used for further processing will all have an impact on the possible presence of biological and chemical contaminants in food and feed products derived from insects.
- (4) While several issues in the EFSA conclusions are addressed by the general and specific hygiene requirements and procedures based on the hazard analysis and critical control points principles in accordance with Articles 4 and 5 of Regulation (EC) No 852/2004 of the European Parliament and of the Council<sup>3</sup>, it is appropriate to lay down specific requirements for substrates for feeding insects and for species of insects intended for human consumption.
- (5) Such specific requirements are needed in order to ensure that food derived from insects is safe and to ensure a smooth functioning of the internal market by means of harmonised conditions for the production of insects intended for human consumption.

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<sup>1</sup> OJ L 139, 30.4.2004, p. 55.

<sup>2</sup> EFSA Journal 2015; 13(10):4257.

<sup>3</sup> Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1).

- (6) Commission Regulation (EU) No 142/2011<sup>4</sup> lays down health rules as regards animal by-products not intended for human consumption. In particular, that Regulation lays down specific requirements for the production of insects intended for the feeding of animals. Since EFSA made similar conclusions for the use of insects in food and feed strict conditions for the primary production of insects intended for human consumption should also be laid down, in particular as regards conditions for the substrate for the feeding of those insects.
- (7) Food consisting of, isolated from or produced from insects or their parts is subject to authorisation in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council and to listing in Commission Implementing Regulation (EU) 2017/2470. It is appropriate to ensure consistency with these Regulations, when laying down specific requirements as regards the species of insects intended for human consumption.
- (8) Annex III to Regulation (EC) No 853/2004 should therefore be amended accordingly.
- (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*

Annex III to Regulation (EC) No 853/2004 is amended in accordance with the Annex to this Regulation.

*Article 2*

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

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*

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<sup>4</sup> Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive (OJ L 54, 26.2.2011, p. 1).