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Delegations will find attached document D067752/03.

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

**of **XXX****

**amending the Annexes to Regulation (EC) No 852/2004 of the European Parliament and  
of the Council on the hygiene of foodstuffs as regards food allergen management,  
redistribution of food and food safety culture**

(Text with EEA relevance)

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

of **XXX**

**amending the Annexes to Regulation (EC) No 852/2004 of the European Parliament and of the Council on the hygiene of foodstuffs as regards food allergen management, redistribution of food and food safety culture**

(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 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 13(1) (c) and (d) thereof,

Whereas:

- (1) Regulation (EC) No 852/2004 lays down general rules for food business operators on the hygiene of foodstuffs taking into account the principle that it is necessary to ensure food safety throughout the food chain, starting with primary production. Food business operators therefore, need to comply with the general hygiene provisions laid down in Annexes I and II of that Regulation.
- (2) On 30 October 2014, the European Food Safety Authority ('the Authority') updated its scientific advice on the evaluation of allergenic foods and food ingredients for labelling purposes<sup>2</sup>, indicating that the presence of food allergies across Europe has been estimated at 3 to 4% for both adults and children. The Authority concluded that, while food allergies affect a relatively small proportion of the population, an allergic reaction can be severe, even potentially fatal and that it is increasingly apparent that people with food allergies or intolerances experience a very significant reduction in quality of life.
- (3) In September 2020, the Codex Alimentarius Commission adopted a code of practice on food allergen management for food business operators (CXC 80-2020) including recommendations on the mitigation of food allergens by a harmonised approach in the food chain based on general hygiene requirements.
- (4) Considering the adoption of the global standard CXC 80-2020 and the expectations of consumers and trade partners that food produced in the EU complies at least with such global standard, it is necessary to introduce requirements introducing good hygiene

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

<sup>2</sup> <http://www.efsa.europa.eu/sites/default/files/consultation/140523.pdf>

practices to prevent or limit the presence of substances causing allergies or intolerances, referred to in Annex II to Regulation (EU) No 1169/2011, in equipment, conveyances and/or containers used for the harvesting, transport or storage of foodstuffs. Since contamination of foodstuffs might take place both at the level of primary production and at stages beyond that production, both Annexes I and II to Regulation (EC) No 852/2004 should be amended.

- (5) The Farm to Fork Strategy for a fair, healthy and environmental friendly food system, adopted by the Commission, is a key component of the European Green Deal initiative. Reducing food waste is one of the objectives of the Farm to Fork Strategy which will also contribute to achieving a circular economy. Redistribution of food surplus for human consumption, in particular through food donations, where it is safe to do so, ensures the highest value use of edible food resources, while preventing food waste.
- (6) On 27 September 2018, the Authority adopted a second scientific opinion on hazard analysis approaches for certain small retail establishments and food donations<sup>3</sup>. In the opinion, it states that food donations presents several new food safety challenges at retail level and therefore it recommends several additional general hygiene requirements. It is therefore necessary to lay down certain requirements in order to promote and facilitate redistribution of food, while guaranteeing its safety for consumers.
- (7) In September 2020, the Codex Alimentarius Commission adopted a revision of its global standard on *General Principles of Food Hygiene* (CXC 1-1969). The revised CXC 1-1969 introduces the “food safety culture” concept as a general principle. Food Safety Culture enhances food safety by increasing the awareness and improving behaviour of employees in food establishments. Such impact on food safety has been demonstrated in several scientific publications.
- (8) Considering the revision of the global standard and the expectations of consumers and trade partners that food produced in the EU complies at least with such global standard, it is necessary to include general requirements on food safety culture in Regulation (EC) No 852/2004.
- (9) Regulation (EC) No 852/2004 should be amended accordingly.
- (10) 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*

Annexes I and II to Regulation (EC) No 852/2004 are amended in accordance with the Annex to this Regulation.

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<sup>3</sup> EFSA Journal 2018; 16(11):5432

*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*  
*Ursula von der LEYEN*