



Brussels, **XXX**
SANTE/10430/2020
[...] (2020) **XXX** draft

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

of XXX

amending Regulation (EC) No 852/2004 of the European Parliament and of the Council on the hygiene of foodstuffs as regards allergens, disposal of food and food safety culture

(Text with EEA relevance)

NON-PAPER of March 2020

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

of XXX

amending Regulation (EC) No 852/2004 of the European Parliament and of the Council on the hygiene of foodstuffs as regards allergens, disposal 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 foodstuffs¹, 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. The Commission may adapt or update the Annexes of the Regulation taking into account technical developments and their practical consequences, consumer expectations with regards to food composition and scientific advice, particularly risk assessments.
- (2) On 14 November 2014, the European Food Safety Authority (EFSA) updated its scientific advice on food allergens², indicating that the prevalence of food allergies across Europe has been estimated at around 1% for both adults and children. While food allergies affect a relatively small proportion of the population, an allergic reaction can be severe, even potentially fatal, and it is increasingly apparent that people with food allergies experience a very significant reduction in quality of life.
- (3) During its meeting from 6 to 11 July 2020, the Codex alimentarius Commission adopted a code of practice on food allergen management for food business operators (RCP...), including recommendations on the mitigation of food allergen by a harmonised approach in the food chain based on general hygiene requirements.
- (4) Article 21 of Regulation (EU) No 1169/2011 of the European Parliament and of the Council³ lays down labelling requirements for certain substances or products causing allergies or intolerances. Considering the adoption of a global standard and the expectations of consumers and trade partners, it is needed to supplement these labelling requirements with general hygiene rules preventing or reducing the contamination of allergens in food. Since such contamination might take place both at primary production

¹ OJ L 139, 30.4.2004, p. 1–54

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³ Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18)

and at stages beyond that production, both Annexes I and II of Regulation (EC) No 852/2004 should be amended.

- (5) The Farm to Fork strategy for Sustainable food is a key component of the European Green Deal. The Farm to Fork Strategy includes the achievement of a circular economy, of which food waste prevention is part. Disposal and redistribution of food surplus for human consumption, in particular food donations, where safe to do so, ensure the highest value use of edible food resources, while preventing food waste.
- (6) On 27 September 2018, EFSA adopted a second scientific opinion on hazard analysis approaches for certain small retail establishments and food donations⁴. The opinion highlights that food donations presents several novel food safety challenges and therefore recommends several additional general hygiene requirements. Laying down such requirements in Regulation (EC) No 852/2004 will promote and facilitate disposal and redistribution of food, while guaranteeing their safety for consumers.
- (7) During its meeting from 6 to 11 July 2020, the Codex alimentarius Commission adopted a revision of the *General Principles of Food Hygiene* (CXC 1-1969). The revised Codex standard introduces food safety culture as a general principle acknowledging the importance of human behaviour in providing safe food, which has been demonstrated in several scientific publications. Consumers and trade partners expect European food business operators to comply at least with global standards.
- (8) It is therefore needed 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

Annex I of Regulation (EC) No 852/2004 is amended as follows:

In Part A, Section II, the following point 5a is added:

'5a. Equipment, conveyances and/or containers used for the harvesting, transport or storage of one of the substances or products causing allergies and intolerances, referred to in Annex II of Regulation (EU) No 1169/2011, shall not be used for the harvesting, transport and storage of any ~~other food, not containing that substance or product, including the other substances and products referred to in that Annex,~~ unless the equipment, conveyances and/or containers have been cleaned and checked for the absence of any visible debris of that substance or product.'

Article 2

Annex II to Regulation (EC) No 852/2004 is amended as follows:

- (1) The introduction is replaced by the following:

'INTRODUCTION

⁴ EFSA Journal 2018; 16(11):5432

Chapters V, VI, VII, VIII, IX, X, XI, XIa and XII apply to all stages of production, processing and distribution of food and the remaining Chapters apply as follows:

- Chapter I applies to all food premises, except premises to which Chapter III applies;
- Chapter II applies to all rooms where food is prepared, treated or processed, except dining areas and premises to which Chapter III applies;
- Chapter III applies to those premises listed in the heading of that Chapter;
- Chapter IV applies to all transportation;
- Chapter Va applies to retail.

(2) The following Chapter Va is added after Chapter V:

' CHAPTER Va

Disposal-Redistribution of food

Food business operators carrying out a retail activity may redistribute food for the purpose of food donations subject to the conditions laid down in points 1 to 4.

1. Food business operators, carrying out a retail activity, shall routinely check the quality of food under their responsibility and may redistribute it in accordance with the requirements in paragraphs 2 and 3:
 - (a) in case of food for which a 'use by' date in accordance with Article 24 of Regulation (EU) No 1169/2011 applies, ~~assure the removal from the market of the food at the latest at~~before the expiry of that date;
 - (b) in case of food for which a date of minimum durability in accordance with Article 2(2)(r) of Regulation (EU) No 1169/2011 applies, ~~dispose of the food in accordance with paragraphs 2 to 4~~-when the date of minimum durability is approaching or passed, or,
 - (b)(c) in case a date of minimum durability or 'use-by' date does not apply, -when the quality of the food can still be ensured at the end of the shelf-life,-
- ~~2. Food business operators handling food that was removed from shelves at retail because approaching the 'use by' date, approaching or passing the date of minimum durability, or showing indications of reducing quality, shall either:~~
 - ~~(a) handle it as food waste in accordance with Chapter VI, or~~
 - ~~(b) ascertain that the food is still safe and suitable for consumption, and further handle the food, including possible processing, in accordance with points 3 and 4.~~
2. Food business operators handling food referred to in paragraph ~~2(b)1~~in particular for the purpose of food donation, shall assess the safety and suitability of such food by taking into account:
 - (a) the date of minimum durability or 'use by' date;
 - (b) the integrity of the packaging, when applicable;

- (c) the proper storage and transport conditions taking into account applicable temperature requirement;
- (d) the date of freezing in accordance with point 2(b) of Section IV to Annex II of Regulation (EC) No 853/2004, when applicable;
- (e) the organoleptic conditions.

3. In order to facilitate the redistribution of food referred to in paragraph 2(b) ~~for food donation purposes~~, such food can be frozen at retail:

- (a) without undue delay to a temperature of -18°C or lower;
- (b) in accordance with ~~the any~~ condition laid down by the competent authorities for freezing and further use as food;
- (c) derogating from point 4 in Chapter VII of Section I as regards meat of ungulates and from point 5 of Chapter V of Section II as regards meat of poultry and lagomorphs, in Annex III to Regulation (EC) No 853/2004 of the European Parliament and of the Council⁵.

(3) In Chapter IX, the following point 9 is added:

‘9 Equipment, conveyances and/or containers used for the processing, handling, transport or storage of one of the substances or products causing allergies and intolerances, referred to in Annex II of Regulation (EU) No 1169/2011, shall not be used for the processing, handling, transport or storage of any ~~other food, not containing that substance or product, including the other substances and products referred to in that Annex,~~ unless the equipment, conveyances and/or containers have been cleaned and checked for the absence of any visible debris of that substance or product.’

(4) The following Chapter XIa is added after Chapter XI:

‘CHAPTER XIa

Food Safety Culture

1. Food business operators shall establish, maintain and provide evidence of an appropriate food safety culture including the following requirements:

- (a) commitment of the management, in accordance with point 2, and all employees to the safe production of food;
- (b) leadership ~~to set the right direction and~~ to engage all employees in food safety practices;
- (c) risk awareness of the importance of food safety and hygiene by all employees in the business;
- (d) open and clear communication between all employees in the business, including communication of deviations and expectations;

⁵ 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 (OJ L 139, 30.4.2004, p. 55).

Kommenterede [DSK(1)]: BE suggestion to put this in the beginning of the Annex II e.g. after Chapter I because general statement on FBO commitment.

Kommenterede [DSK(2)]: Propose to delete by BE since very vague, but it is the wording of the Codex General Principles of Food Hygiene.

(e) the availability of sufficient resources to ensure the safe and hygienic handling of food.

2. The management commitment shall include:

- (a) ensuring that roles and responsibilities are clearly communicated in the food business;
- (b) maintaining the integrity of the food hygiene system when changes are planned and implemented;
- (c) verifying that controls are working and documentation is up to date;
- (d) ensuring the appropriate training and supervision are in place for personnel;
- (e) ensuring compliance with relevant regulatory requirements;
- (f) Encouraging continual improvement, where appropriate, taking into account developments in science, technology and best practices.

Article 3

This Regulation shall enter into force on the 20th 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 LETEN

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