

COMMISSION REGULATION (EU) 2021/382**of 3 March 2021****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 ⁽¹⁾, 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 ⁽²⁾, 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 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 ⁽³⁾. 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.

⁽¹⁾ OJ L 139, 30.4.2004, p. 1.

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

⁽³⁾ *EFSA Journal* 2018; 16(11):5432

- (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.

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, 3 March 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

- (1) Annex I to Regulation (EC) No 852/2004 is amended as follows:

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

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

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

- (a) the introduction is replaced by the following:

INTRODUCTION

Chapters V, Va, VI, VII, VIII, IX, X, XI, XIa and XII apply to all stages of production, processing and distribution of food. 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,;

- (b) the following Chapter Va is inserted after Chapter V:

CHAPTER Va

Redistribution of food

Food business operators may redistribute food for the purpose of food donation subject to the following conditions:

- (1) Food business operators shall routinely check if food under their responsibility is not injurious to health and is fit for human consumption in accordance with Article 14(2) of Regulation (EC) No 178/2002 (*). If the check carried out is satisfactory, food business operators may redistribute food in accordance with point (2):
- for food for which a “use by” date is applied in accordance with Article 24 of Regulation (EU) No 1169/2011, before the expiry of that date,
 - for food for which a date of minimum durability is applied in accordance with Article 2(2)(r) of Regulation (EU) No 1169/2011, up to and after that date, or
 - for food for which a date of minimum durability is not required in accordance with point 1(d) of Annex X to Regulation (EU) No 1169/2011, at any time provided.
- (2) Food business operators handling food referred to in point 1, shall assess if food is not injurious to health and fit for human consumption by taking into account at least the following:
- the date of minimum durability or the “use by” date, ensuring sufficient remaining shelf-life left to allow for the safe redistribution and use by the final consumer,
 - the integrity of the packaging, when applicable,
 - the proper storage and transport conditions, including applicable temperature requirements,
 - the date of freezing in accordance with point 2(b) of Section IV of Annex II to Regulation (EC) No 853/2004 of the European Parliament and of the Council (**), when applicable,
 - the organoleptic conditions,

- the assurance of traceability in accordance with Commission Implementing Regulation (EU) No 931/2011 (**), in case of products of animal origin.

- (*) 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).
- (**) 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).
- (***) Commission Implementing Regulation (EU) No 931/2011 of 19 September 2011 on the traceability requirements set by Regulation (EC) No 178/2002 of the European Parliament and of the Council for food of animal origin (OJ L 242, 20.9.2011, p. 2).;

(c) in Chapter IX, the following point 9 is inserted:

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

(d) the following Chapter XIa is inserted after Chapter XI:

CHAPTER XIa

Food Safety Culture

1. Food business operators shall establish, maintain and provide evidence of an appropriate food safety culture by fulfilling the following requirements:
 - (a) commitment of the management, in accordance with point 2, and all employees to the safe production and distribution of food;
 - (b) leadership towards the production of safe food and to engage all employees in food safety practices;
 - (c) awareness of food safety hazards and 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, within an activity and between consecutive activities, including communication of deviations and expectations;
 - (e) availability of sufficient resources to ensure the safe and hygienic handling of food.
2. Management commitment shall include:
 - (a) ensuring that roles and responsibilities are clearly communicated within each activity of the food business;
 - (b) maintaining the integrity of the food hygiene system when changes are planned and implemented;
 - (c) verifying that controls are being performed timely and efficiently and documentation is up to date;
 - (d) ensuring that the appropriate training and supervision are in place for personnel;
 - (e) ensuring compliance with relevant regulatory requirements;
 - (f) encouraging continual improvement of the food safety management system of the business, where appropriate, taking into account developments in science, technology and best practices.
3. The implementation of the food safety culture shall take account of the nature and size of the food business.'