

Commission Regulation (EU) No 284/2011 of 22 March 2011 laying down specific conditions and detailed procedures for the import of polyamide and melamine plastic kitchenware originating in or consigned from the People's Republic of China and Hong Kong Special Administrative Region, China

COMMISSION REGULATION (EU) No 284/2011

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laying down specific conditions and detailed procedures for the import of polyamide and melamine plastic kitchenware originating in or consigned from the People's Republic of China and Hong Kong Special Administrative Region, China

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules⁽¹⁾, and in particular Article 48(1) thereof,

Whereas:

- (1) Commission Directive 2002/72/EC⁽²⁾ lays down specific provisions relating to plastic materials and articles intended to come into contact with foodstuffs, including compositional requirements, and restrictions and specifications for substances that may be used therein.
- (2) Several notifications and alerts have been received by the Rapid Alert System for Food and Feed pursuant to Article 50 of Regulation (EC) No 178/2002 of the European Parliament and of the Council⁽³⁾ concerning food contact materials imported into the Union from the People's Republic of China (hereinafter 'China') and Hong Kong Special Administrative Region of the People's Republic of China (hereinafter 'Hong Kong'), releasing into food or food simulant amounts of chemicals that are not in compliance with the Union legislation.
- (3) These notifications and alerts primarily concern polyamide and melamine plastic kitchenware that does not comply with the requirements concerning the release of primary aromatic amines and formaldehyde into food as laid down in Part A of Annex V and Section A of Annex II to Directive 2002/72/EC respectively.
- (4) Primary aromatic amines (hereinafter 'PAA') are a family of compounds, some of which are carcinogenic, while others of these compounds are suspected carcinogens. PAA may arise in materials intended for food contact as a result of the presence of impurities or breakdown products.
- (5) Polyamide kitchenware originating in or consigned from China and Hong Kong has been reported to release high level of PAA into food.

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- (6) Directive 2002/72/EC authorises the use of formaldehyde in the manufacture of plastics, provided that these plastics do not release into food more than 15 mg/kg of formaldehyde (specific migration limit (SML) expressed as total formaldehyde and hexamethylenetetramine).
- (7) Melamine kitchenware originating in or consigned from China and Hong Kong has been reported to release into food levels of formaldehyde that are higher than those authorised.
- (8) In the past few years, in order to increase knowledge of the requirements set out in Union legislation concerning food contact materials imported into the Union, the Commission has taken several initiatives, including training sessions for Chinese control authorities and the industry concerned.
- (9) Despite those initiatives, the missions of the Food and Veterinary Office to China and Hong Kong in 2009 identified serious deficiencies in the official control system regarding plastic food contact materials intended for importation into the Union and large quantities of controlled polyamide and melamine plastic kitchenware originating in or consigned from China and Hong Kong still do not fulfil the requirements of Union legislation.
- (10) Regulation (EC) No 1935/2004 of the European Parliament and of the Council⁽⁴⁾ lays down specific provisions relating to the materials and articles intended to come into contact directly or indirectly with food, including certain general and specific requirements that these materials and articles should fulfil. Pursuant to Article 24 thereof, Member States shall carry out official controls in order to enforce compliance with that Regulation in accordance with the relevant provisions of Union law relating to official food and feed controls. Those provisions are laid down in Regulation (EC) No 882/2004.
- (11) More specifically, Article 48(1) of Regulation (EC) No 882/2004 provides that in so far as Union legislation does not lay down the conditions and detailed procedures to be respected when importing goods from third countries, they may, if necessary, be laid down by the Commission.
- (12) Article 48(2) of Regulation (EC) No 882/2004 provides for the possibility to impose specific import conditions on particular products coming from certain third countries, taking into account the risks associated with these products.
- (13) In order to minimise the health risks that may arise from polyamide and melamine plastic kitchenware originating in or consigned from China or Hong Kong, each consignment of such products should be accompanied by appropriate documentation, including analytical results showing that it meets the requirements concerning the release of PAA and formaldehyde respectively, as laid down in Directive 2002/72/EC.
- (14) In order to ensure a more efficient organisation of the controls of polyamide and melamine plastic kitchenware originating in or consigned from China or Hong Kong, the importers or their representatives should give prior notification of the arrival and of the nature of the consignments. Likewise, Member States should have the possibility

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to designate specific first points of introduction through which consignments of these articles may enter the Union. This information should be publicly available.

- (15) In order to ensure a degree of uniformity at the Union level with regard to the controls of polyamide and melamine plastic kitchenware originating in or consigned from China or Hong Kong, the procedure for the official controls, as defined in Article 2 of Regulation (EC) No 882/2004, should be defined in this Regulation. These controls should include documentary, identity and physical checks.
- (16) In the event of non-compliance being identified during the physical checks, Member States should immediately inform the Commission through the Rapid Alert System for Food and Feed.
- (17) Member States should have the possibility, in specific cases, to authorise the onward transportation of consignments of polyamide and melamine plastic kitchenware originating in or consigned from China or Hong Kong from the first point of introduction, provided arrangements are made with the competent authority at the point of destination to ensure the traceability of the consignments pending the results of the physical checks, in order to allow the competent authority to deal with the process of importing such consignments effectively and efficiently.
- (18) The release into free circulation of polyamide and melamine plastic kitchenware originating in or consigned from China or Hong Kong should take place only once all the checks have been completed and the results are known. For that purpose the result of the controls should be made available to the customs authorities before the goods can be released for free circulation.
- (19) A procedure for recording the information obtained from these controls should be established. This information should be submitted regularly to the Commission.
- (20) The provisions of this Regulation should be periodically reviewed, taking into account the information received from the Member States.
- (21) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter

This Regulation lays down specific conditions and detailed procedures for the import of polyamide and of melamine plastic kitchenware originating in or consigned from the People's Republic of China (hereinafter 'China') and Hong Kong Special Administrative Region of the People's Republic of China (hereinafter 'Hong Kong').

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Article 2

Definitions

For the purpose of this Regulation the following definitions shall apply:

- (a) ‘plastic kitchenware’ means plastic materials as described in paragraphs 1 and 2 of Article 1 of Directive 2002/72/EC and falling within CN code ex 3924 10 00;
- (b) ‘consignment’ means a quantity of polyamide or melamine plastic kitchenware, covered by the same document(s), conveyed by the same means of transport and coming from the same third country;
- (c) [^{F1}“competent authorities” means the competent authorities of Great Britain designated in accordance with Article 4 of Regulation (EC) No. 882/2004;
- (d) “first point of introduction” means the point of entry of a consignment into Great Britain;]
- (e) ‘documentary check’ means the checking of the documents referred to in Article 3 of this Regulation;
- (f) ‘identity check’ means a visual inspection to ensure that the documents accompanying the consignment tally with the contents of the consignment;
- (g) ‘physical check’ means the sampling for analysis and laboratory testing and any other check necessary to verify compliance with the requirements concerning the release of PAA and formaldehyde laid down in Directive 2002/72/EC.

Textual Amendments

- F1** Art. 2(c)(d) substituted (31.12.2020) by [The Food and Feed Imports \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/664\)](#), regs. 1, **19** (as amended by [S.I. 2020/1504](#), regs. 1(2), **13(6)**); 2020 c. 1, Sch. 5 para. 1(1)

Article 3

Import conditions

1 Polyamide and melamine plastic kitchenware originating in or consigned from China and Hong Kong shall be imported into [^{F2}Great Britain] only if the importer submits to the competent authority for each consignment a declaration, duly completed, confirming that it meets the requirements concerning the release of primary aromatic amines and formaldehyde laid down in Part A of Annex V and in Section A of Annex II to Directive 2002/72/EC respectively.

2 A model of the declaration referred to in paragraph 1 is set out in the Annex to this Regulation. The declaration [^{F3}must be drawn up in English, or in English and Welsh].

3 The declaration referred to in paragraph 1 shall be accompanied by a laboratory report providing:

- a as regards polyamide kitchenware, analytical results demonstrating that they do not release into foods or food simulants primary aromatic amines in a detectable quantity.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 284/2011. (See end of Document for details)

The detection limit applies to the sum of primary aromatic amines. For the purpose of the analysis the detection limit for primary aromatic amines is set at 0,01 mg/kg food or food simulants;

- b as regards melamine kitchenware, analytical results demonstrating that they do not release into foods or food simulants formaldehyde in a quantity exceeding 15 mg/kg food.

4 The competent authority shall indicate in the declaration set out in the Annex to this Regulation, whether the goods are acceptable or not for release into free circulation, depending on whether they fulfil the terms and conditions provided for in Directive 2002/72/EC as set out in paragraph 1.

Textual Amendments

- F2** Words in Art. 3(1) substituted (31.12.2020) by [The Food and Feed Imports \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/664\)](#), regs. 1, **20(a)** (as substituted by [S.I. 2020/1504](#), regs. 1(2), **13(7)**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F3** Words in Art. 3(2) substituted (31.12.2020) by [The Food and Feed Imports \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/664\)](#), regs. 1, **20(b)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 4

Prior notification of consignments

Importers or their representatives shall notify the competent authority at the first point of introduction at least two working days in advance of the estimated date and time of physical arrival of consignments originating in or consigned from China and Hong Kong.

^{F4}Article 5

Notification of the first point of introduction

Where the appropriate authority decides to designate specific first points of introduction for consignments originating in or consigned from China and Hong Kong, the appropriate authority and the Food Safety Authority must publish an up-to-date list of these points.]

Textual Amendments

- F4** Art. 5 substituted (31.12.2020) by [The Food and Feed Imports \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/664\)](#), regs. 1, **21**; 2020 c. 1, Sch. 5 para. 1(1)

Article 6

Controls at the first point of introduction

- 1 The competent authority at the first point of introduction shall carry out:
 - a documentary checks on all consignments within two working days from the time of their arrival;

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 284/2011. (See end of Document for details)

- b identity and physical checks, including laboratory analysis of 10 % of consignments, and in such a way that it is not possible for the importers or their representatives to predict whether any particular consignment will be subjected to such checks; the results of physical checks must be available as soon as technically possible.

[^{F52} If the laboratory analysis referred to in point (b) of paragraph 1 identifies non-compliance, the competent authorities must immediately inform the Food Safety Authority and the appropriate authority of the results.]

Textual Amendments

F5 Art. 6(2) substituted (31.12.2020) by [The Food and Feed Imports \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/664\)](#), regs. 1, **22**; 2020 c. 1, Sch. 5 para. 1(1)

Article 7

Onward transportation

The competent authority at the first point of introduction may authorise the onward transportation of the consignments originating in or consigned from China and Hong Kong, pending the results of the checks referred to in point (b) of Article 6(1).

If the competent authority grants the authorisation referred to in the first paragraph, it shall notify the competent authority at the point of destination and shall supply a copy of the declaration set out in the Annex, duly completed as provided in Article 3 and the results of the checks referred to in point (b) of Article 6(1), as soon as the latter are available.

[^{F6} Competent authorities must ensure that consignments remain under their continuous control and cannot be tampered with in any way pending the results of the checks mentioned in point (b) of Article 6(1).]

Textual Amendments

F6 Words in Art. 7 substituted (31.12.2020) by [The Food and Feed Imports \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/664\)](#), regs. 1, **23**; 2020 c. 1, Sch. 5 para. 1(1)

Article 8

Release for free circulation

The release for free circulation of polyamide and melamine plastic kitchenware originating in or consigned from China and Hong Kong is subject to the presentation to the customs authorities of the declaration set out in the Annex duly completed as provided for in Article 3.

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Article 9

Reporting ^{F7} ...

1 When checks referred to in Article 6(1) are performed, the competent authorities shall keep records of the following information:

- a details of each consignment checked, including:
 - (i) the size in terms of number of articles;
 - (ii) the country of origin;
- b the number of consignments subject to sampling and analysis;
- c the results of the controls referred to in Article 6.

[^{F82} Competent authorities must submit to the appropriate authority and the Food Safety Authority a report including the information referred to in paragraph 1, quarterly by the end of the month following each quarter.]

Textual Amendments

- F7** Words in [Art. 9](#) heading omitted (31.12.2020) by virtue of [The Food and Feed Imports \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/664\)](#), regs. 1, **24(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F8** [Art. 9\(2\)](#) substituted (31.12.2020) by [The Food and Feed Imports \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/664\)](#), regs. 1, **24(b)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 10

Entry into force

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

This Regulation shall apply from 1 July 2011.

^{F9} ...

Done at Brussels, 22 March 2011.

For the Commission

The President

José Manuel BARROSO

Textual Amendments

- F9** Words in [Signature](#) omitted (31.12.2020) by virtue of [The Food and Feed Imports \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/664\)](#), regs. 1, **25**; 2020 c. 1, Sch. 5 para. 1(1)

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) No 284/2011. (See end of Document for details)*

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ANNEX

Declaration to be provided for every consignment of polyamide and melamine plastic kitchenware originating in or consigned from the People's Republic of China and Hong Kong Special Administrative Region, China^{F10}

Textual Amendments

F10 Annex: words "Great Britain" substituted for the words "the Union" in both places it occurs (31.12.2020) by [The Food and Feed Imports \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/664\)](#), regs. 1, **26** (as amended by [S.I. 2020/1504](#), regs. 1(2), **13(8)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 284/2011. (See end of Document for details)

Name and full address (including telephone or e-mail address) of the natural or legal person issuing this declaration	
Name and full address (including telephone or e-mail address) of the business operator(s) which manufacture(s) the plastic kitchenware of the consignment	
Name and full address (including telephone or e-mail address) of the business operator which is responsible for the first introduction in the Union of the consignment	
<p>Identification code of the consignment:</p> <p>Type and number of articles in the consignment:</p> <p>This consignment contains plastic kitchenware made of:</p> <p><input type="checkbox"/> polyamide — Analytical tests have been carried out demonstrating that the articles do not release PAA in a detectable quantity</p> <p>— The detection limit of the method used is</p> <p>— The results of these tests as well as the description of the method of analysis used are attached to this document</p> <p><input type="checkbox"/> melamine — Analytical tests have been carried out demonstrating that the articles do not release formaldehyde in a quantity exceeding the SML of 15 mg/kg</p> <p>— The results of these tests as well as the description of the method of analysis used are attached to this document</p>	
List of documents annexed confirming that the consignment meets the requirements concerning the release of primary aromatic amines or formaldehyde laid down in Directive 2002/72/EC:	
The undersigned, as importer in the Union of the consignment, confirms that such consignment meets the requirements concerning the release of primary aromatic amines or formaldehyde laid down in Directive 2002/72/EC	<p>Place and date</p> <p>Name of signatory</p> <p>Signature</p> <p>Full address (including telephone and e-mail address)</p>
Declaration of the competent authority on the consignment:	<p>Acceptable for release into free circulation:</p> <p><input type="checkbox"/> Conforms</p> <p><input type="checkbox"/> Does not conform</p> <p>Place and date</p> <p>Name of signatory</p> <p>Signature</p> <p>Full address (including telephone and e-mail address)</p>

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- (1) OJ L 165, 30.4.2004, p. 1.
- (2) OJ L 220, 15.8.2002, p. 18.
- (3) OJ L 31, 1.2.2002, p. 1.
- (4) OJ L 338, 13.11.2004, p. 4.

Changes to legislation:

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