Food Standards Agency
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To: Heads of Environmental Health Departments
Heads of Trading standards Departments
Port Health Authorities

22.04.2010

Dear colleagues,

NEW DRAFT COMMISSION REGULATION ON IMPORTED FOOD CONTACT MATERIALS FROM CHINA – FOR INFORMATION

1. The European Commission has proposed a new regulation relating to the importation of specific plastic kitchen ware from the Peoples Republic of China and Hong Kong into Member States.

2. This was in response to several alerts raised via the Rapid Alert System for Food and Feed (RASFF) - pursuant to Article 50 of Regulation 178/2002 - on Food Contact Materials coming from China and feedback from Member States in July 2009 which were subsequently confirmed by two Food and Veterinary Office (FVO) missions to China.

3. This draft Regulation applies specifically to nylon kitchen ware and melamine ware. Nylon kitchen ware originating in or consigned from, China and Hong Kong has been found to release high levels of primary aromatic amines (PAA) into foods. PAAs are a family of compounds some of which are carcinogenic and could potentially pose health risk to consumers. Furthermore, melamine ware originating in or consigned from China and Hong Kong has been found to release formaldehyde into foods at levels higher than 15mg/kg as authorised under Directive 2002/72/EC, as amended.

4. You may wish to note that Article 48(2) of Regulation 882/2004, as amended, provides for the imposition of specific import conditions on particular products coming from certain third countries depending on the risks associated with these products.

5. The UK intends to apply Article 27 of OFFC Regulation 882/2004/EC such that costs for the conditions imposed by this regulation will be borne by the importers of the kitchen ware concerned.

6. The key aspects of this draft regulation are as follows:

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- Each consignment shall be accompanied by an attestation with, basically, the same information as the Declaration of Compliance (DoC) required under Directive 2002/72/EC as amended.

- 50% of all consignments shall be sampled and analysed. Nylon kitchenware shall be tested for PAA migration- with detection limit set at 0.1mg/kg while melamine kitchenware shall be tested for formaldehyde migration expected not to exceed 15 mg/kg food

7. It is proposed that the Regulation shall come into force on 01 January, 2011.

   I attach a copy of the full text of the draft for your information.

   Should you wish to express any view(s) on it or require further information, please contact me not later than **05 May, 2010** by email:

   kwabena.andam@foodstandards.gsi.gov.uk

Yours faithfully,

Kwabena Andam

Higher Scientific Officer (Pesticides, Nitrates & Food Contact Materials)

Food Safety: Contaminants & Novel Foods Division

Tel.: 0207 276 8772

SANCO/10320/2010

EUROPEAN COMMISSION

Brussels,

Draft

COMMISSION REGULATION (EU) No …/..

of […]

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

Draft

COMMISSION REGULATION (EU) No …/..

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laying down specific conditions and detailed procedures for the import of plastic kitchenware originating in or consigned from 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 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC[1] and in particular Article 24 thereof;

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[2], and in particular Article 48 (2) thereof,

Whereas:

(1) Commission Directive 2002/72/EC[3] lays down specific provisions relating to plastic materials and articles intended to come into contact with foodstuffs, including compositional requirement, and restrictions and specifications for substances that can be used therein.

(2) Several notifications and alerts have been received by the Rapid Alert System for Food and Feed (hereinafter - RASFF) pursuant to Article 50 of Regulation 178/2002[4] on food contact materials imported into the European 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), concerning the non-compliance of these materials with the Union legislation.

(3) In particular, these notifications and alerts concern plastic kitchenware which does not comply with the requirements set out in Commission Directive 2002/72/EC.

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

(4) Primary aromatic amines (hereinafter - PAA) are a family of compounds some of which are carcinogenic, 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) Nylon kitchenware originating in or consigned from China and Hong Kong has been reported through the RASSF to release high level of PAA into food.

(6) Formaldehyde is a monomer the use of which in the manufacture of plastics is authorised under Directive 2002/72/EC. However, plastics should not release into food more than 15 mg/kg of formaldehyde.

(7) Melamine kitchenware originating in or consigned from China and Hong Kong has been reported to release higher than authorised levels of formaldehyde into food.

(8) In the last few years, in order to raise the knowledge about 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 (hereinafter - FVO) to China and Hong Kong in 2009 showed serious deficiencies in the official control system regarding plastic food contact materials intended for importation into the Union and a high number of controlled plastic kitchenware originating in or consigned from China and Hong Kong still does not fulfil the requirements of the Union legislation.

(10) According to Article 48 (1) of Regulation (EC) No 882/2004 to the extent that the conditions and detailed procedures to be respected when importing goods from third countries are not provided for by Union legislation, they may, if necessary, be laid down by the Commission.

(11) 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, according to the risks associated to these products.

(12) In order to minimize the health risks that may arise from plastic kitchenware originating in or consigned from China or Hong Kong, each consignment of such products should be accompanied by appropriate documentation declaring that it complies with Directive 2002/72/EC.

(13) In addition, as regards nylon and melamine kitchenware specific analytical documents should be provided to ensure that they do not release into food quantities of PAA and formaldehyde which could endanger human health.

(14) In order to ensure that a uniform level of checks is carried out by Member States, a percentage of consignments of plastic kitchenware originating in or consigned from China or Hong subject to physical controls should be established.

(15) A procedure for recording the information obtained from physical checks should be established. This information should be submitted regularly to the Commission.

(16) Member States should immediately inform the Commission of unfavourable control results through the RASFF.

(17) The provisions of this Regulation should be periodically reviewed, taking into account the information received from the Member States.

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 plastic plastic kitchenware originating in or consigned from China and Hong Kong pursuant to Article 24 of Regulation (EC) No 1935/2004 and Article 48 of Regulation (EC) No 882/2004.

Article 2

Definitions

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

(a) "plastic kitchenware" means plastic materials within the definition of Article1.2 and 1.3 of Directive 2002/72/EC and referred to with CN code 3924 10.

(b) ‘consignment’ means a quantity of plastic kitchenware, covered by the same document(s), conveyed by the same means of transport and coming from the same third country.

(c) "competent authorities" means competent authorities of the Member States designated in accordance with Article 4 of Regulation (EC) No 882/2004.

(d) "physical check" means the sampling for analysis and laboratory testing and any other check necessary to verify compliance with Directive 2002/72/EC.

Article 3

Import conditions

1. 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) shall be imported into the Member States only if the importer provides for each consignment a declaration, referred to in Article 9 of Directive 2002/72/EC, confirming that it meets the relevant requirements laid down in that Directive.

2. A model of the declaration mentioned in paragraph 1 containing the relevant information referred to in Annex VIa of Directive 2002/72 is set out in the Annex. The declaration shall be drawn up in the official language, or in one of the official languages, of the Member State where the consignment is imported.

3. Details on the conditions and results of testing, calculations, other analysis, and evidence on the safety or reasoning demonstrating compliance with the requirements laid down in Directive 2002/72/EC shall be joined to the declaration, referred to in paragraph 1.

4. In addition to the documentation, referred to in paragraphs 1, 2 and 3, the consignments of plastic kitchenware made of nylon and of melamine shall also be accompanied by:

(a) as regards nylon kitchenware, analytical results demonstrating that they do not release into foods primary aromatic amines in a detectable quantity. For the purpose of the analysis the detection limit for primary aromatic amines is set at 0,01 mg/kg food;

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

Article 4

Sampling and analysis

1. The competent authorities shall perform physical checks of 50% of consignments of plastic kitchenware, originating in or consigned from China and Hong Kong presented for import to ascertain that the consignments conform to what is declared in the accompanying documents.

2. Member States shall inform immediately the Commission and the other Member States of unfavourable results of the controls, provided in paragraph 1 through the Rapid Alert System for Food and Feed provided under Article 50 of Regulation (EC) No 178/2002.

3. When physical checks referred to in paragraph 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 objects,

(ii) the country of origin;

(b) the number of consignments subject to sampling and analysis;

(c) the results of the controls, provided in Article 4(1).

4. Member States shall submit to the Commission a report including the information referred to in paragraph 3, quarterly by the end of the month following each quarter.

Article 5

Entry into force

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

The Regulation shall apply to consignments reaching the border from the date of application.

This Regulation shall apply from 1 January 2011.

This Regulation shall be binding in its entirety and directly applicable in all Member States in accordance with the Treaties.

Done at Brussels, […]

For the Commission
The President

ANNEX

Declaration to be provided for every consignment of plastic kitchenware originating in or consigned from People's Republic of China and Hong Kong Special Administrative Region, China

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 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 export of the plastic kitchenware of the consignment	
Specifications on the use of the articles present in the consignment.	
List of documents annexed to this declaration to demonstrate compliance with Directive 2002/72/EC:	
The undersigned, person responsible for the consignment, confirms that the plastic kitchenware present therein meets the relevant requirements laid down in Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with foodstuffs	**Place and date** **Name of signatory** **Signature**