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HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Directorate E- Safety of the Food chain

E6- Innovation and sustainability

EU guidelines on conditions and procedures for the import of polyamide and melamine kitchenware originating in or consigned from People's Republic of China and Hong Kong Special Administrative Region, China

VERSION 1

NOTE

This guidance has been endorsed by the Member States in the Standing Committee of the Food Chain and Animal Health, Section Toxicological Safety of the Food Chain on 10.06.2011.

For questions please contact SANCO-FCM@ec.europa.eu.

This document is an evolving document and will be updated to take account of the experience of the competent authorities and of other information provided.

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1. INTRODUCTION

The purpose of this document is to provide guidance on the application of 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 People's Republic of China and Hong Kong Special Administrative Region, China¹. The Regulation (EU) No 284/2011 aims to ensure uniform import procedures at EU level of kitchenware made of polyamide and melamine originated or consigned in China and Hong Kong regarding the release of primary aromatic amines (PAA) and formaldehyde.

In particular, the guidelines seek to:

- clarify the applicable provisions of Regulation (EC) No 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules². This is the basic act from which Regulation (EU) No 284/2011 takes its legal basis,
- provide other legal clarifications,
- provide Member States and business operators with some guidelines regarding the implementation of certain provisions, e.g. examples of specific cases when Member States could decide to allow onward transportation; actions in case of non-compliance,
- provide guidance on how competent authorities and customs authorities should collaborate,
- provide a common approach/methodology for testing and sampling conditions of the articles regarding the detection limit of primary aromatic amines and the migration limit of formaldehyde in plastic kitchenware, as developed by the EU Reference Laboratories (EU RL)³ network,
- provide guidance to Member States on how to send the quarterly report to the Commission as provided for in Article 9 of Regulation (EU) No 284/2011.

2. CLARIFICATIONS ON PARTICULAR ISSUES

2.1. What is polyamide and melamine plastic kitchenware?

Polyamide and melamine plastic kitchenware are plastic kitchenware defined by CN code 3924 10 00 which consist completely of polyamide or melamine or which consist of parts intended to come into contact with food that are made of polyamide or melamine.

Melamine refers to formaldehyde based resins with melamine and/or urea.

2.2. What is a consignment and what is a lot?

¹ OJ L 77, 23.3.2011, p. 25.

² OJ L 165, 30.4.2004. p. 1.

³ As established by Article 32 of Regulation 882/2004.

A 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.

A consignment can arrive at the first point of introduction in one container, in several containers, or only as part of one container together with other consignments.

A consignment can consist of articles that differ in shape, size, print pattern, food contact areas and/or conditions of uses. A lot means a stated portion of the consignment to be tested for the migration of primary aromatic amines or formaldehyde. A lot consists of a number of a given article or of sets of articles with a corresponding reference or item number or code and a description in the delivery document (For sampling strategies on consignments and lots consult the technical guidelines).

2.3. Legal basis: Article 48(1) of Regulation (EC) No 882/2004

Article 24 of Regulation (EC) No 1935/2004 → Union law relating to official food and feed controls → **Regulation (EC) No 882/2004 (Article 48 (1))**

Regulation (EC) No 1935/2004⁴ lays down specific provisions relating to 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 the 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 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules⁵.

Regulation (EC) No 882/2004 covers feed and food and also more specific areas in the whole food chain, including materials in contact with food, as set out in its Recital 3. The application of the controls established on the basis of 882/2004 should ensure the compliance of food contact materials with Regulation (EC) No 1935/2004.

Based on this premise, specific import conditions in the form of a Regulation for food contact materials as such can be adopted as a means to ensure monitoring of their compliance with Regulation (EC) No 1935/2004, and Article 48(1) of Regulation 882/2004 is therefore the relevant legal basis.

Article 48 of Regulation (EC) No 882/2004

1. To the extent that the conditions and detailed procedures to be respected when importing **goods** from third countries or their regions are not provided for by Community law and in particular by Regulation (EC) No 854/2004, they shall, if necessary, be laid down by the Commission. Those measures, designed to **amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 62(4).**

⁴ OJ L 338, 13.11.2004, p. 4.

⁵ OJ L 165, 30.4.2004, p.1.

2. The conditions and detailed procedures referred to in paragraph 1 may include:
- (a) the establishment of a list of third countries from which specific products may be imported into one of the territories referred to in Annex I;
 - (b) the establishment of **models of certificates accompanying consignments**;
 - (c) **special import conditions**, depending on the type of product or animal and the possible risks associated therewith.
- [...]
5. When adopting the special import conditions referred to in paragraph 2(c), account shall be taken of information that the third countries concerned have provided and, where necessary, the **results of Community controls carried out in such third countries. Special import conditions may be established for a single product or for a group of products. They may apply to a single third country, to regions of a third country, or to a group of third countries.**

2.4. Why Article 15(5) of Regulation (EC) No 882/2004 is not the legal basis of Commission Regulation (EU) No 284/2011

Article 15(5) of Regulation (EC) No 882/2004 could not be used as the legal basis for this Regulation because it states the following: “A list of **feed and food of non-animal origin** that is, on the basis of known or emerging risk, to be subject to an increased level of official controls at the point of entry into territories referred to in Annex I shall be drawn up and updated, in accordance with the procedure referred to in Article 62(3).”

It appears from the letter of Article 15(5) that the list can only be used if the measure concerns feed and food. Commission Regulation (EC) No 669/2009 implementing Regulation (EC) No 882/2004 of the European Parliament and of the Council as regards the **increased level of official controls on imports of certain feed and food of non-animal origin** and amending Decision 2006/504/EC⁶, takes Article 15(5) of Regulation (EC) No 882/2004 as its legal basis.

Without prejudice to the different legal basis, the provisions established by both Regulations are quite similar. However, Regulation (EC) No 669/2009 provides a more exhaustive explanation of the official controls to be applied. It establishes for example:

- Minimum requirements for points of entry, which are compulsory, e.g. the allocation of specific facilities and equipment for the storage and control of the consignments.
- A common entry document (CED) to be completed by the business operators and by the competent authorities confirming the completion of official controls.
- Possibility to perform, under special circumstances, physical checks at the premises of feed and food business operators.
- Obligations for feed and food business operators to facilitate the checking of the consignments.
- Consignments could be split only after the increased level of controls has been completed.
- Provisions regarding non-compliance.

⁶ O L 194, 25.7.2009, p. 11.

- Provisions on fees.

The reading of Articles 17, 19, 20, 21, 22, 24 in conjunction with Article 15 (5) of Regulation (EC) No 882/2004 allows the establishment of the above related provisions. This was not the case for Regulation (EU) No 284/2011, which has a limited scope to regulate import conditions only.

2.5. Differences between "designated point of entry" set out in Regulation (EC) No 669/2009 and "first point of introduction" set out in Regulation (EU) No 284/2010

From a strict legal point of view, "designated points of entry" and "first points of introduction" are not the same but could in practice be the same physical point. They perform similar tasks: documentary, identity and physical checks.

- Regulation (EC) No 669/2009, which is based in Article 15(5) of Regulation (EC) No 882/2004, provides for increased level of official controls at the designated points of entry.

These points are designated by Member States for that purpose.

- Regulation (EU) No 284/2011 provides for specific conditions and procedures for the import at the first point of introduction,

The first point of introduction is the point of entry of a consignment into the Union and Member States do not necessarily have to designate specific points of introduction.

2.6. Correlation table in view of the repeal of Commission Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with foodstuffs⁷ by Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food⁸

Regulation (EU) No 10/2011 repealed Directive 2002/72/EC on 1 May 2011. The references made in Regulation (EU) No 284/2011 to Directive 2002/72/EC should be considered as made to Regulation (EU) No 10/2011 **since 1 May 2011**.

The following table reflects the correspondence of the relevant articles between the two legal measures as regards Regulation (EU) No 284/2011.

Directive 2002/72/EC	Regulation (EU) No 10/2011
Article 1, paragraph 1 and 2: Definition of plastic materials: 1. (not relevant) 2. This Directive shall apply to the following materials and articles which, in	Article 2 Scope 1. This Regulation shall apply to materials and articles which are placed on the EU market and fall under the following categories: (a) materials and articles and parts thereof

⁷ OJ L 220, 15.8.2002, p. 18.

⁸ OJ L 12, 15.1.2011, p. 1.

<p>the finished product state, are intended to come into contact or are brought into contact with foodstuffs and are intended for that purpose (hereafter referred to as ‘plastic materials and articles’):</p> <p>(a) materials and articles and parts thereof consisting exclusively of plastics;</p> <p>(b) plastic multi-layer materials and articles;</p> <p>(c) plastic layers or plastic coatings, forming gaskets in lids that together are composed of two or more layers of different types of materials.</p>	<p>consisting exclusively of plastics;</p> <p>(b) plastic multi-layer materials and articles held together by adhesives or by other means;</p> <p>(c) materials and articles referred to in points a) or b) that are printed and/or covered by a coating;</p> <p>(d) plastic layers or plastic coatings, forming gaskets in caps and closures, that together with those caps and closures compose a set of two or more layers of different types of materials;</p> <p>(e) plastic layers in multi-material multi-layer materials and articles.</p>
<p>Part A of Annex V (requirements for release of primary aromatic amines):</p> <p>Plastic material and articles shall not release primary aromatic amines in a detectable quantity (DL= 0.01 mg/kg of food or food simulant).</p> <p>The migration of the primary aromatic amines appearing in the lists in Annex II and III is excluded from this restriction</p>	<p>Annex II, point 2 (requirements for release of primary aromatic amines):</p> <p>Plastic materials and articles shall not release primary aromatic amines, excluding those appearing in Table 1 of Annex I, in a detectable quantity into food or food simulant. The detection limit is 0.01 mg of substance per kg of food or food simulant. The detection limit applies to the sum of primary aromatic amines release.</p>
<p>Section A of Annex II (requirements for release of formaldehyde)</p> <p>17260/ 000050-00-0/ Formaldehyde/ SML(T) = 15 mg/kg (22)</p>	<p>Annex I, Table 1 (requirements for release of formaldehyde)</p> <p>98/17260 or 54880/000050-00-0/formaldehyde/yes/yes/no/.../(15)/.../...</p> <p>(15): FCM substance 98 (formaldehyde) and 196(hexamethylenetetramine): SML is 15 mg/kg food expressed as formaldehyde</p>

3. RELEVANT PROVISIONS OF REGULATION (EC) NO 882/2004

Regulation (EU) No 284/2011 supplements Regulation (EC) No 882/2004. The following provisions are applicable in the framework of the implementation of Regulation (EU) No 284/2011.

3.1. Article 2: Definition of “competent authorities”

“Competent authority” means the central authority of a Member State competent for the organisation of official controls or any other authority to which that competence has been conferred; it shall also include, where appropriate, the corresponding authority of a third country.

3.2. Title II, Chapter II: Competent authorities

Articles 4, 5, 6, 7 and 8 of Regulation (EC) No 882/2004 should be taken into account by Member States when establishing competent authorities at the first point of introduction for the purpose of the import controls established by Regulation (EU) No 284/2011.

3.3. Title II, Chapter VI: Financing of official controls

Certain provisions on fees under Regulation (EC) No 882/2004 are applicable to the import controls defined in Regulation (EU) No 284/2011 and should be taken into account by Member States when deciding on the specific fees to be applied.

Regulation (EC) No 882/2004 introduces a voluntary system of fees or charges that Member States may collect when performing this specific type of official controls.

Fees in respect of the official controls set up by Regulation (EU) No 284/2011 should therefore be established at the discretion of the Member States.

Articles 27, 28 and 29 of Regulation 882/2004 are the applicable provisions to be taken into consideration by Member States when establishing their fees:

Article 27 Fees or charges

1. Member States may collect fees or charges to cover the cost occasioned by official controls.

[...]

4. Fees collected for the purposes of official controls in accordance with paragraph 1 or 2:

a) shall not be higher than the costs borne by the responsible competent authorities in relation to the items listed in Annex VI;

[...]

5. In setting the fees, Member States shall take into consideration:

(a) the type of business concerned and relevant risk factors;

(b) the interests of businesses with a low throughput;

(c) traditional methods used for production, processing and distribution;

(d) the needs of businesses located in regions subject to particular geographical constraints.

[...]

8. Fees relating to import controls are to be paid by the operator or his representative to the competent authority in charge of import controls.

9. Fees shall not directly or indirectly be refunded, unless unduly collected.

10. Without prejudice to the costs deriving from the expenses referred to in Article 28, **Member States shall not collect any fees other than those referred to in this Article for the implementation of this Regulation.**

11. Operators or other relevant businesses or their representatives shall receive proof of their payment of fees.

12. The Member States shall make public the method of calculation of fees and communicate it to the Commission. The Commission shall examine whether the fees comply with the requirements of this Regulation.

Article 28 Expenses arising from additional official controls

When the detection of non-compliance leads to official controls that exceed the competent authority's normal control activities, the competent authority shall charge the operators responsible for the non-compliance, or may charge the operator owning or keeping the goods at the time when the additional official controls are carried out, for the expenses arising from the additional official controls. Normal control activities are the routine control activities required under Community or national law [...]. Activities that exceed normal control activities include the taking and analysis of samples as well as other controls that are required to check the extent of a problem, to verify whether corrective action has been taken, or to detect and/or substantiate non-compliance.

Article 29 Level of expenses

When setting the level of expenses referred to in Article 28, account shall be taken of the principles laid down in Article 27.

Annex VI CRITERIA TO BE TAKEN INTO CONSIDERATION FOR THE CALCULATION OF FEES

1. The salaries of the staff involved in the official controls.
2. The costs for the staff involved in the official controls, including facilities, tools, equipment, training, travel and associated costs.
3. The laboratory analysis and sampling costs.

Note: The controls made at the first point of introduction as set out in Regulation (EU) No 284/2011 should be considered as “normal control activities”. Further actions derived from the detection of non-compliance (See point 4.14 of this guidance document) should be seen as activities that exceed normal control activities.

3.4. Title VII: Enforcement measures

The general actions to be followed in cases where non compliant products are detected are set out in Article 54 of Regulation (EC) No 882/2004:

Article 54: Action in case of non-compliance

1. When the competent authority identifies non-compliance, it shall take action to ensure that the operator remedies the situation. When deciding what action to take, the competent authority shall take account of the nature of the non-compliance and that operator's past record with regard to non-compliance.
2. Such action shall include, where appropriate, the following measures:
[...]
(e) the suspension of operation or closure of all or part of the business concerned for an appropriate period of time;
[...]
(h) any other measure the competent authority deems appropriate.

3. The competent authority shall provide the operator concerned, or a representative, with:

(a) written notification of its decision concerning the action to be taken in accordance with paragraph 1, together with the reasons for the decision;

and

(b) information on rights of appeal against such decisions and on the applicable procedure and time limits.

4. Where appropriate, the competent authority shall also notify the competent authority of the Member State of dispatch of its decision.

[...]

4. GUIDANCE REGARDING THE APPLICATION OF CERTAIN PROVISIONS OF REGULATION (EU) No 284/2011

For the purpose of having uniform conditions and procedures for import, the following suggestions aim at providing Member States with guidance that would enable the uniform implementation of some articles in the Regulation (EU) No 284/2011.

4.1. Designation of first points of introduction

The specific controls set up by Regulation (EU) No 284/2011: documentary, identity and physical checks will take place at the first points of introduction.

Article 5 of Regulation (EU) No 284/2011 provides that Member States may decide to designate specific first points of introduction for the consignments of melamine and polyamide kitchenware from China and Hong Kong. If they so wish, Member States are free to designate specific first points of introduction depending, for example, on the volume of imported consignments.

The designated specific first points of introduction are available on the SANCO webpage:

http://ec.europa.eu/food/food/chemicalsafety/foodcontact/documents_en.htm

4.2. The meaning of “as soon as technically possible” in Art. 6(1)(b)

“As soon as technically possible” may signify a different timeline depending on the laboratory capacities of each Member State and the analyses to be performed.

4.3. Declaration as regards compliance of the goods

A. Requirements under Regulation (EU) No 284/2011

For the purpose of the specific conditions and import procedures set up in Regulation (EU) No 284/2011, each consignment made of polyamide and melamine plastic kitchenware originating in or consigned from China and Hong Kong arriving at the EU border as from 1 July 2011 intended to be imported and therefore released for free circulation must be accompanied by a Declaration confirming that it meets the requirements with regard to the release of primary aromatic amines and formaldehyde set out for plastic food contact materials and articles.

The model set out in the Annex to Regulation (EU) No 284/2011 should be used for such purpose.

B. Requirements under Regulation (EC) No 1935/2004

As a general requirement for all plastic materials and articles placed on the market in the EU Article 15 of Regulation (EU) No 10/2011 provides that a Declaration of Compliance in accordance with Article 16 of Regulation (EC) No 1935/2004 needs to be available at the marketing stages other than retail stages. The Declaration of compliance has to contain the information laid down in Annex IV of Regulation (EU) 10/2011.

The business operator has the obligation to keep documentation to demonstrate that the plastic materials and articles comply with the requirements of the Regulation and to make this documentation available to the national competent authorities on request.

4.4. Can the Declaration be submitted to the competent authorities electronically?

The completed Declaration including attachments can be submitted to the competent authorities on paper or in electronic form. However, in order to introduce uniform and clear methods of monitoring imports, the establishment of electronic systems are highly recommended.

The model of the Declaration is downloadable in all EU languages from the DG SANCO website at the following website:

http://ec.europa.eu/food/food/chemicalsafety/foodcontact/documents_en.htm

4.5. Could the Declaration be accepted in all official languages of the Member States?

The Declaration should be filled out in the official language, or one of the official languages, of the Member State into which the consignment is imported.

Where onward transportation to another Member State is allowed and the goods are intended to be released for free circulation in that Member State, it is recommended to present to the competent authorities an additional copy of the Declaration in the language of the Member State where the products are intended to be released for free circulation in order to facilitate the administrative procedures between the competent authorities at the first point of introduction and the competent and customs authorities at the point of destination.

4.6. Is a Declaration necessary for goods introduced into the EU that are not intended to be released for free circulation?

A Declaration is needed only for goods arriving at the first point of introduction as from 1 July 2011 intended to be **imported**⁹ and therefore, released for free circulation into the EU, regardless of when the goods left China or Hong Kong:

⁹ Import is defined in Article 2.15 of Regulation 882/2004. As regards food contact materials in the context of Regulation (EU) No 284/2011, import means the release for free circulation of goods, or

Article 48(1) of Regulation (EC) No 882/2004 refers to “conditions and detailed procedures to be respected when **importing** goods from third countries”. On the other hand, Article 1 of Regulation (EU) 284/2011, as currently drafted, refers to “specific conditions and detailed procedures for the **import** of polyamide and of melamine plastic kitchenware originating 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)”.

The following are examples of different possible cases:

Case 1: Non-EU goods placed under customs transit procedure that are likely to be declared for the release for free circulation in the EU, as the intended office of destination in the original transit declaration is within the EU.

In this case, this consignment is subject to special import conditions under Regulation (EU) No 284/2011 and a Declaration is to be requested.

Case 2: Non-EU goods placed under a customs external transit procedure simply crossing the EU territory (for example non-EU goods from CH to Russia or trucks loaded in the port of Rotterdam and destined for Russia).

In this case, this consignment is **not** subject to the special import conditions laid down by Regulation (EU) No 284/2011 and the Declaration is not needed.

Case 3: Non- EU goods placed in a free zone and afterwards re-exported

In this case, this consignment is **not** subject to special import conditions laid down by Regulation (EU) No 284/2011 and the Declaration is not needed.

4.7. The laboratory report supporting the Declaration

To support the Declaration a laboratory report that is representative for the consignment has to be available. If the laboratory report is representative for several consignments because they were produced with the same materials under the same production conditions the test report can be the same but needs to accompany each consignment.

4.7.1. Do all items (different shapes and patterns of articles) of the consignment need to be tested and the test results included in the laboratory report?

If the laboratory report covers a representative sample of items that also has different print patterns, shapes or contact areas then this report can be attached to all the items for which it is representative. If the laboratory report covers a representative sample of items tested under worst conditions of use where the items have different conditions of use then this report can be attached to all the items for which it is representative. The description must be clear, and supplemented with supporting pictures/ photographs where necessary. Also in this case it should be clearly stated that the report is

the intention to release the goods for free circulation, i.e. to confer to non-Union goods the customs status of Union goods. This entails the application of commercial policy measures, completion of the other formalities laid down in respect of the importation of goods and the charging of any duties legally due.

representative for the shipped consignment. It is recommended that the laboratory report mentions the batch and/or lot number of the articles for which it is representative.

4.8. Splitting of consignments

Consignments should not be split until the checks have been favourably completed, and the Declaration has been filled in by the competent authority as provided for in Article 3(4) of Regulation (EU) No 284/2011.

In the case of subsequent splitting of the consignment, an authenticated copy of the Declaration and of the report of the checks shall accompany each part of the consignment until it is released for free circulation.

4.9. Specific cases where Member States can authorise onward transportation

In accordance with Article 7 and Recital 17 of Regulation (EU) No 284/2011, 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, pending the results of the physical checks. Provided that the consignment stays under continuous control of competent authorities until physical checks are finalised and arrangements are made with the competent authority at the point of destination to ensure the traceability of the consignments Member States may authorise onward transportation. The consignment should be appropriately identifiable at the place of destination as being not for placing on the market until the completed declaration is issued. This prerogative should help the competent authority to deal with the process of importing such consignments effectively and efficiently.

In case of onward transportation to another Member State arrangements should be made with the place of destination to ensure that the consignment is not placed on the market until the competent authority at first point of introduction has a guarantee that fees based on Article 27 of Regulation (EC) No 882/2004 have been or will be paid.

The authorisation of onward transportation should be issued only when justified by specific circumstances. Possible examples of such circumstances are:

- Physical and space reasons: when there is no physical space at the first point of introduction
- Financial reasons: to allow the business operator to make a proper use of the market opportunities and to gain time as regards the distribution of the goods; where storage costs at the first point of introduction are significantly higher than at the place of destination and thus lead to unfair competition for business operators whose consignment is subject to physical tests compared to business operators whose consignment is not.

In any case the final decision on whether to allow onward transportation is to be taken by the competent authority at the first point of introduction.

4.10. What should be the reaction of the competent authority in case it is informed that a consignment has been imported into the EU but the consignment has not been presented for official controls?

The consignment should be considered as if it was not in compliance with Regulation (EU) No 284/2011. The competent authority should order that it be recalled or withdrawn and placed under official detention without delay and that it be then re-dispatched (see Point 4.14).

4.11. What happens if a business operator who initially does not intend to declare the goods for the release for free circulation changes his mind afterwards?

Consignments of non-EU goods introduced into the EU which have not undergone the checks required by Article 6 of Regulation (EU) No 284/2011 (because they were not originally indicated as intended to be released for free circulation) cannot be accepted for release for circulation by customs authorities).

If the business operator changes its initial intention as regards the destination of the goods and decides that he wants to declare the goods for the release for free circulation, then the business operator should inform customs authority at a point of introduction and present the Declaration to the responsible competent authorities in accordance with Article 3 of Regulation (EU) No 284/2011 and the consignment needs to undergo the checks required in Article 6.

4.12. What happens if a consignment, which is presented to the customs authorities for its release for free circulation, is not accompanied by a Declaration as provided for in Article 3 of Regulation (EU) No 284/2011?

Consignments that are not accompanied by a Declaration in accordance with Article 3 of Regulation (EU) No 284/2011, and which have not undergone the checks required by Article 6 cannot be accepted for release for free circulation.

Competent authorities may grant the business operator who is responsible for the first introduction of the consignment into the Union a limited time frame, to be decided by the competent authority, to provide the Declaration.

4.13. What should competent authorities do if the documentary checks provided for in Article 6(1)(a) of the Regulation are unsatisfactory and/or incomplete?

Documentary checks are unsatisfactory and/or incomplete when the information provided in the Declaration and its annexes show that the goods in the consignment do not comply with Regulation (EU) No 284/2011, e.g. the goods have not been tested in the country of origin; the results of the analytical test attached to the Declaration show that the goods have not been adequately tested; the results of the analytical tests are not satisfactory; the information regarding the analytical test is missing for the whole or part of the consignment; part of the consignment is mentioned in the Declaration but no supporting documents are provided.

In such cases, the competent authorities may request further information from the business operator who is responsible for the first introduction of the consignment into the

Union or from the importer, if they are one and the same to be provided within a time-frame to be decided by the competent authority depending on which documents are missing.

If unsatisfactory or insufficient information is provided to the competent authority, the consignment should be considered non-compliant and measures under point 4.14 could be taken.

The Declaration should then be completed by the competent authority by indicating that these goods are not acceptable for release for free circulation (tick box "Does not conform").

4.14. Actions for competent authorities where goods are non-compliant following the identity and physical checks provided for in Article 6(1)(b) of Regulation (EU) No 284/2011

Actions on goods which do not comply with EU legislation are to be taken in line with Regulation (EC) No 882/2004. In the context of Regulation (EU) No 284/2011, the actions provided for in Regulation (EC) No 882/2004 can be interpreted as follows.

A consignment is considered not in compliance if the physical check of one test specimen (1 out of 3 tested specimen representative of a lot) fails to comply with the limits set out in Regulation (EU) No 10/2011.

If the results of the identity and physical checks establish non-compliance of the consignment, the responsible officials of the competent authority should complete the Declaration accordingly (tick box "Does not conform") and could take some of the following actions depending on the nature of the non-compliance and the past record of that operator with regard to non-compliance:

4.14.1. Official detention and subsequent actions

The competent authority should place under official detention a consignment that does not comply with the applicable food contact materials legislation and, having heard the business operators responsible for the consignment; it could take the following measures:

- (a) order that such plastic kitchenware be destroyed, in particular in cases where the consignment is injurious to human health or is unsafe;
- (b) order that such plastic kitchenware be re-dispatched outside the Union in line with point 4.14.4 ;
- (c) order that such polyamide kitchenware be shredded and melted within or outside the EU under controlled conditions and formed into articles for purposes other than for food contact;

4.14.2. Notification to RASFF

Where the competent authority does not permit the import of plastic kitchenware, it should notify the Commission and other Member States of its findings and of the identification of the products concerned in accordance with the **Rapid Alert System** procedure, and should notify its decisions to the customs services, together with information as regards the final destination of the consignment.

(Please note that, while the options in points 4.14.1, 4.14.3 and 4.14.4 are possible actions for Member States, the notification to RASFF is mandatory as established in Article 6(2) of Regulation (EU) No 284/2011).

4.14.3. Right of appeal

Decisions on consignments should be subject to the right of appeal. The competent authorities should provide the business operator with information on rights of appeal against its decisions.

(Please note that this right is contained in Article 54 of Regulation 882/2004 and therefore is applicable, for the purpose for the implementation of Regulation (EU) No 284/2011).

4.14.4. Re-dispatch of consignments

The competent authority could allow re-dispatch of consignments only if:

- (a) the destination has been agreed with the business operator responsible for the consignment; and
- (b) the business operator has first informed the competent authority of the third country of origin or third country of destination, if different, of the reasons and circumstances preventing the placing on the market of the articles concerned within the Union; and
- (c) when the third country of destination is not the third country of origin, the competent authority of the third country of destination has notified the competent authority that it is prepared to accept the consignment.

Re-dispatch should take place within 60 days after the day on which the competent authority decided on the destination of the consignment, unless legal action has been taken.

Competent authorities shall cooperate to take any further measures necessary (in addition to the notification to RASFF) to ensure that it is not possible for the rejected consignments to be reintroduced into the Union.

4.15. Indications on how competent authorities should document the results of the documentary, identity and physical checks provided for in Article 6(1) of Regulation (EU) No 284/2011

After the completion of the checks provided for in Article 6(1) of Regulation (EU) No 284/2011 the competent authority should:

- a) complete the last box of the Declaration (either in the original provided by the business operator responsible for the first introduction or in a copy);
- b) make and keep a copy of the duly completed Declaration;
- c) annex a copy of the report of the identity and physical checks to the Declaration;
- d) provide the completed Declaration and the report of the identity and physical checks to the business operator responsible for the introduction;
- e) in cases where onward transportation is allowed, the competent authority will send the completed Declaration and the report of the identity and physical checks, when these become available to the competent authority of destination, which shall provide them to the business operator responsible for the introduction.

The original of the Declaration completed by the competent authority and the reports of the checks shall accompany the consignment until the time of release for free circulation.

4.16. Indications on how to complete the Declaration

General: Please complete the Declaration in capitals

A separate Declaration must be completed for each consignment presented at the first point of introduction, whenever the consignment is intended for free circulation in the EU.

First part of the Declaration (first six rows and corresponding columns): This part must be completed by the importer or by the business operator responsible for the first introduction into the Union, if they are the same.

“Business operator”: Means the natural or legal person(s) responsible for ensuring that the requirements of the food contact materials regulations are met within the business under its supervision.

The **“Business operator which manufactures plastic kitchenware”** will be responsible for ensuring that the requirements of plastic regulations are met during the manufacturing process, in particular for those products to be placed at the EU market.

The **“Business operator which is responsible for the first introduction in the Union of the consignment”** will be responsible for ensuring that the plastic kitchenware it intends to import into the EU complies with the regulations on food contact materials.

A business operator responsible for the first introduction could intend to import goods into the EU or could only intend to introduce goods in transit, customs warehousing, inward processing, processing under customs control and temporary admission that will need to be checked only if they are ultimately intended for release for free circulation.

Identification code of the consignment: this code should be provided by the business operator and may be composed of the container number or seal number of the container

Under **type and number of articles in the consignment** the batch or lot numbers of the articles in the consignment can be listed in addition to the description of the articles.

Import: Means the release for free circulation of plastic kitchenware or the intention to release plastic kitchenware for free circulation. Release for free circulation shall confer on non-Union goods the status of Union goods. It shall entail application of commercial policy measures, completion of other formalities laid down in respect of the importation of goods and the charging of any duties legally due.

Importer: Means the business operator that intends to import the goods into the Union. The importer will be responsible for ensuring that the requirements of plastics regulations are met, and in particular those of Regulation No 284/2011. The importer could be the same natural or legal person as the business operator responsible for the first introduction of the consignment into the Union.

Second part of the Declaration (7th row with corresponding columns): This part must be completed by the designated competent authorities.

5. COMPETENT AUTHORITIES AND CUSTOMS AUTHORITIES: COLLABORATION PURSUANT TO ARTICLE 8 OF REGULATION (EU) No 284/2011

Goods can only be released for free circulation by the customs authorities subject to the presentation of the Declaration conforming to the Annex to Regulation (EU) No 284/2011 and duly completed by the business operator and the competent authority. The competent authority must certify that the consignment does “Conform”.

The following collaboration scheme should be followed:

- The competent authorities at the first point of introduction are in charge of the checks as set out in Article 6 of Regulation (EU) No 284/2011.
- Once the checks have been performed, the competent authority should complete the Declaration and return it to the business operator responsible for the introduction.
- The business operator will present the Declaration to the customs authorities when the goods are intended to be released for free circulation
- For the decision on acceptance of the release for free circulation of goods, the customs authorities will take due account of the information provided in the Declaration as completed by the competent authorities.

5.1. Principles governing the collaboration between competent authorities and customs authorities

Customs authorities to verify that consignments comply with the Regulation (EU) No 284/2011

Customs authorities should ensure that only plastic kitchenware subject to the Regulation (EU) No 284/2011 for which a Declaration is presented, are accepted for release for free circulation. This will be ensured through the linkage of the Regulation (EU) No 284/2011 with the Customs clearance systems of the Member States through the EU TARIC-database (TARIC = Integrated Community Tariff). The TARIC database includes duty rates, restrictions and control measures that have to be respected at importation or exportation of goods and is integrated into the electronic customs clearance systems of Member States. It also makes economic operators aware of the requirement to present the “Declaration” referred to in the Annex.

The Regulation (EU) No 284/2011 has been linked to new TARIC-Codes (3924 10 00 11 and 392410 00 19).

Mutual support

Whenever necessary, customs authorities should be able to contact the competent authorities (have the necessary information whom to contact) for assistance or clarification by the appropriate means for the case in question. The same applies to competent authorities, who should contact customs authorities whenever questions about customs matters need to be clarified. Arrangements between the authorities should be put in place for that purpose.

5.2. Legal framework as regards customs controls:

With regard to customs controls that are carried out to support the implementation of the Regulation (EU) No 284/2011, the general principles laid down in the Union's customs legislation apply:

➤ **Community Customs Code: COUNCIL REGULATION (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code**

Consolidated version as of 20 November 2006:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1992R2913:20070101:EN:PDF>

➤ **Implementing Provisions relating to the Community Customs Code: COMMISSION REGULATION (EEC) No 2454/93 of 2 July 1993 laying down provisions for the implementation of Council Regulation (EEC) No 2913/92 establishing the Community Customs Code**

Consolidated version of 20 May 2010:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1993R2454:20100701:EN:PDF>

5.3. Legal framework as regards conditions and procedures for import of polyamide and melamine kitchenware originating from China and Hong Kong:

➤ **Rules on official controls: 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**

Consolidated version of 28 June de 2009:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2004R0882:20090807:EN:PDF>

➤ **Implementing provision of Regulation on official controls: 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 People's Republic of China and Hong Kong Special Administrative Region, China**

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:077:0025:0029:EN:PDF>

6. GUIDANCE ON A COMMON APPROACH/METHODOLOGY FOR TESTING PRIMARY AROMATIC AMINES (PAAs) AND FORMALDEHYDE IN PLASTIC KITCHENWARE

The EU Reference Laboratory¹⁰, in cooperation with National Reference Laboratories¹¹ has prepared technical guidance on sampling methodologies of consignments of kitchenware, including methods for testing of PAA and the expression of test results

6.1. Guidelines on testing the migration of primary aromatic amines from polyamide kitchenware and for formaldehyde from melamine kitchenware

The technical guidelines on testing of migration are available at the following website http://ihcp.jrc.ec.europa.eu/our_labs/eurl_food_c_m

¹⁰ As established in Article 32 of Regulation (EC) No 882/2004. EU Reference Laboratories are listed in Annex VII to this Regulation.

¹¹ As established in Article 33 of Regulation (EC) No 882/2004.

6.2. Which primary aromatic amines should be taken into account when measuring the detection limit?

The **sum of primary aromatic amines** to be taken into account should not include those appearing in Table I of Annex I to Regulation (EU) No 10/2011:

➤ Article 3(3)(a) of Regulation (EU) No 284/2011 establishes that, as regards polyamide kitchenware, **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.

➤ Article 3(1) of Regulation (EU) No 284/2011 establishes that polyamide and melamine plastic kitchenware originating or consigned from China and Hong Kong shall be imported into the EU only if it complies with the requirements concerning the release of primary aromatic amines laid down in Part A of Annex V of Directive 2002/72/EC which provides that “Plastic material and articles shall not release primary aromatic amines in a detectable quantity (DL = 0,01 mg/kg of food or food simulant). **The migration of the primary aromatic amines appearing in the lists in Annex II and III is excluded from this restriction**”.

➤ Since 1 May 2011, Regulation (EU) No 10/2011 applies. The reference made in Article 3 of Regulation (EU) No 284/2011 to Part A of Annex V of Directive 2002/72/EC should be read as referring to the equivalent provisions of Regulation (EU) No 10/2011. Therefore Point 2 of Annex II (Restrictions on materials and articles) therein should be taken into account when measuring which primary aromatic amines are to be detected:

“2. Plastic materials and articles shall not release primary aromatic amines, **excluding those appearing in Table 1 of Annex I**, in a detectable quantity into food or food simulant. The detection limit is 0.01 mg of substance per kg of food or food simulant. The detection limit applies to the sum of primary aromatic amines released.”

At present, primary aromatic amines are not listed in Table 1 of Annex I to Regulation (EU) No 10/2011.

Where primary aromatic amines of this type are listed in Table 1 of Annex I to Regulation (EU) No 10/2011, they should not be taken into account for the purposes of measuring the detection limit of primary aromatic amines in the plastic kitchenware in question.

6.3. Indications on how to verify the compliance with the detection limits of primary aromatic amines

Article 3(3) a) of Regulation (EU) No 284/2011 states that “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**”.

Article 3(3) b) Regulation (EU) No 284/2011 states that “analytical results demonstrating that they do not release into foods or food simulants formaldehyde in a quantity exceeding 15 mg/kg **food**”.

This different approach to analysing the detection limit of primary aromatic amines and the migration limit of formaldehyde derives from the need to be consistent with the approach followed by Commission Regulation (EU) No 10/2011, which refers to a detection limit in “food or food simulants” for PAAs, and to a migration limit into “food” for formaldehyde (Please see point 2.5).

6.4. Decision on non-compliance of the consignment after physical check

A consignment is considered not in compliance if the physical check of one test specimen (1 out of 3 tested specimen representative of a lot) fails to comply with the limits set out in Regulation (EU) No 10/2011.

7. REPORTING TO THE COMMISSION (ARTICLE 9)

Purpose of reporting

The reporting should enable the Commission and Member States to verify the effectiveness of the measure. It will be used to monitor the rate of compliance to non-compliance of the melamine and polyamide kitchenware subject to the Regulation. A review of the measure will be performed at regular intervals on the basis of the reporting.

What needs be reported?

Article 9 of (EU) No 284/2011 provides that details of each consignment checked shall be reported, including

- (1) the size in terms of number of articles, the country of origin;
- (2) the number of consignments subject to sampling and analysis; and
- (3) the results of controls (documentary, identity and physical checks).

Member States shall submit to the Commission a report including this information.

How will the reporting system work?

Reporting will be performed by means of a standard reporting template that competent authorities will submit to a central database system.

The competent authorities can *fill* the report template continuously following the arrival of imported consignments and *submit* at regular intervals or only once by the end of the month following each quarter. Member States can decide to fill in the report template at local level or at central level. The link to the central database system will be made available to Member States at the latest by September 2011.

When to be reported?

Member States shall submit to the Commission a report quarterly by the end of the month following each quarter. The first reporting deadline is end of October 2011 and concerns the checks of consignments imported during July, August and September 2011.