EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Safety of the Food chain
Innovation and sustainability

Brussels, 30.05.2012
SANCO/E6/AS

EMB/1149

DRAFT COMMISSION SERVICES WORKING DOCUMENT

IN PREPARATION OF

Union Guidelines on Regulation (EU) No 10/2011 as regards information in the supply chain

Version 1.0

Please note that this draft Commission working document is the outcome of the discussion of a dedicated technical working group of experts from Member States and Industry and does not necessarily represent the views of the European Commission.

The working document contains in two sections (highlighted on page 18 and on page 21/22) alternatives for the wording. In these two cases no consensus could be found by the experts participating in the working group. The discussion in the working group of Member States experts should in particular focus on these sections to come to a conclusion on the wording.

Comments on the document should be provided by 31 July 2012 to:

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1. INTRODUCTION

This Guidance covers information to be generated and exchanged in the supply chain as required in the context of compliance with Regulation (EU) No 10/2011 "Plastics Regulation".

Specifically, it addresses:

- the aim of the Declaration of Compliance (DoC)
- the Declaration of Compliance (DoC) for plastic materials and articles – set out in Article 15 and Annex IV of the "Plastics Regulation";
- Adequate information on coatings, adhesives and inks which become part of plastic materials and articles (hereinafter "Adequate Information"). For coatings, printing inks and adhesives to be used in plastic materials and articles adequate information should be provided to the manufacturer of the final plastic article that would enable him to ensure compliance for substances for which migration limits have been established in the plastics Regulation.

It also explains the link of DoC with the "Framework Regulation" (EC) No 1935/2004 and the Regulation on Good Manufacturing Practice (GMP) (EC) No 2023/2006 "GMP Regulation".

It should be noted that this guidance does not cover DoC for materials and articles already in contact with food.

Where appropriate, this guidance mentions certain aspects related to supporting documentation or to the labelling provisions of the Framework Regulation or to documentation requirements under GMP, however it does not aspire to cover these topics in depth (See box on page 4). The competent authorities of Member States also can request documentation on the food contact material of packaged food based on Article 10 of Regulation (EC) No 882/2004 on official food and feed control "Control Regulation". Certain Member States have set out national requirements for DoC for other materials. These are not subject of this guidance but need to be respected in cases where the national law is applicable.

2. AIM OF THE DOC

The compliance of the final plastic material and article can only be ensured if along the supply chain relevant **information exchange** takes place between the supplier and the customer and vice versa.

The declaration of compliance is a document delivered by the supplier to his customer. It has two main aims:

- It confirms to the customer the compliance of the product with the relevant requirements of the Plastics Regulation and the Framework Regulation.
- It provides the customer with relevant information necessary for him to establish or check the compliance of his product

Examples for supporting documents

- DoC received from the supplier
- Results on migration test performed
- Composition of a material
- Formulation of a material
- Toxicological information on a substance

In order to allow the exchange of relevant information the requirements on the DoC are set out in a standard format in Annex IV of the Plastics Regulation. This document provides guidance which information is to be provided at the different stages to fulfil these requirements.

The DoC and the "Adequate Information" have to be issued in a language that is easily understood by the supplier and the customer. The information given has to be clear and distinct. Information should relate to the actual composition of the material. E.g. several materials with different composition cannot be covered by one DoC[1] Misleading or inconclusive information have to be avoided.

[1] Information (i.e. affecting the DoC or adequate information) which arises from batch to batch variation should be highlighted to the customer. Identical materials or articles which differ only in colour or printings may be covered by one DoC.

If a general disclaimer is to be provided in the DoC, this cannot invalidate the statements made in the DoC itself.

The DoC is an important tool in the establishment of compliance of the final plastic article with the requirements of the Plastics Regulation and the Framework Regulation. A DoC can only be issued on the basis of information about the product for which it is issued. This information includes all the compliance work that has been performed by the business operator issuing the DoC and is called the "**Supporting Documents**" (Article 16 of the Plastics Regulation). The "Supporting Documents" are generated and kept by the business operator who is issuing the DoC. They are not passed along the supply chain but should be made available to the competent authorities on request. The DoC which the business operator receives from his supplier will become part of his "Supporting documents" together with other information such as test results he has been generating for his product.

The manufacturer of the final plastic material or article has to issue a DoC for his product that may be composed of plastic layers and non-plastics such as adhesives, printing inks and coatings. For components of the plastic layers he will receive DoCs. For the non-plastics parts the Plastics Regulation does not set out an obligation to issue a DoC. However, as the Plastics Regulation requires that migration of authorised substances and certain other substances should not exceed the established migration limits it is necessary that "Adequate Information" is provided by the manufacturers of adhesives, printing inks and coatings that allows the manufacturer of the final plastic article to establish compliance with the Plastics Regulation for these substances. This guidance establishes the information that should be provided by manufacturers of adhesives, printing inks and coatings to the plastics converters.

The DoC and the "Adequate Information" are a confirmation of the compliance work performed by the business operator issuing the document. Compliance work covers the assessment of the hazard of substances added, generated or present in the material together with its potential to migrate into the food. The compliance work that can be performed is dependent on the position of the business operator in the supply chain and the information that is available to the business operator. The roles and obligations of the different business operators, as far as relevant for issuing a DoC, will be explained in point 3 of this guidance. Point 4 of this guidance explains which information needs to be provided in the DoC based on the position of the business operator in the supply chain.

What can be part of the compliance work?

- Verification of authorisation status of an intentionally added substance
- Verification of purity criteria of an intentionally added substance
- Identification and risk assessment of non-intentionally added substances
- Verification of compliance with SML and OML through screening or verification methods

A key problem of complex manufacturing processes is that usually no single stage can perform the complete compliance work: information on chemical composition, presence of not-intentionally added substances such as impurities and degradation products, plastic processing conditions, composition of the food, storage and contact conditions, etc. are not all known at every step of the supply chain. Therefore an **optimized exchange of information** is key to ensure the compliance of the final article. In other words, communication up and down in the supply chain can help to identify relevant information that allows suppliers and customers to adequately perform their own compliance work. It also helps to build **trust** which is essential as the DoC does not duplicate all the information contained in the operator's Supporting Documents.

DECLARATION OF COMPLIANCE AND ITS LINK WITH THE "FRAMEWORK REGULATION" AND THE "GMP REGULATION"

Labelling requirements (Article 15 Framework Regulation)

The DoC is not the only document that is aimed at providing information from supplier to customer on the appropriate use of the plastic article. The **labelling requirements** of the Framework Regulation require that materials and articles not yet in contact with food should be, if necessary, be accompanied with special instructions for safe and appropriate use.

Traceability (Article 17 Framework Regulation)

Every business operator has to establish a traceability system which allows the identification of the business operator from which he received its goods and to which business operator he supplied his goods. The goods must be identifiable to allow their traceability by means of labelling or relevant documentation.

Stating compliance with the Framework Regulation

Stating compliance with the Framework Regulation not only covers the safety aspects set out in Article 3(1)(a) but also covers the following aspects even if not stated explicitly in the DoC:

- that the company is operating under **good manufacturing practice** as set out in the Framework Regulation and in the GMP Regulation
- that the company is operating a **traceability** system
- that the material or article is does not induce an **unacceptable change** in the **composition of the food** or cause a deterioration in the **organoleptic properties of the food**

Stating compliance with Good manufacturing practice

Stating compliance with good manufacturing practice covers in particular the following aspects:

- that **starting materials are selected** and comply with pre-selected specifications that ensure the compliance of the finished article with the Plastics Regulation and the Framework Regulation
- that **operations are carried out** in accordance with pre-established instructions and procedures to ensure the compliance of the finished article with the Plastics Regulation and the Framework Regulation
- that a **quality assurance system** is established
- that a **quality control system** is established

Information on the selection criteria applied to starting materials (such as identity, purity, toxicological profile) is in particular relevant for substances not subject to authorisation and listing in the Annex. Information on operation procedures is in particular relevant for reaction and degradation products. All information generated in the quality assurance and the quality control system needs to be documented and will become part of the "**Supporting Documents**" of the DoC.

Principles for sharing compliance work throughout the production chain

1. Avoid duplication of compliance work

It should be avoided that producers perform the same compliance work on the same material. In order to minimize duplications and costs as much compliance work as possible should be concluded at an early stage.

2. Responsibility of business operators for their manufacturing step with a view to compliance of the finished article under the intended or foreseeable uses

The compliance of the finished article can only be ensured if all business operators in the chain, from the manufacturer of starting substances down to the food packer assume the necessary responsibility for their manufacturing step with a view to the compliance of the finished article. This follows from the obligation that the whole manufacturing process respects GMP. It means that only components suitable for use in food contact materials can be used. This also excludes that a business operator can transfer to his customer all responsibility for compliance work arising from his manufacturing step (general disclaimers).

3. Responsibility of the business operator that introduces or generates a substance in the manufacturing process

A business operator introducing or generating a substance in a product (raw material, intermediate or finished material or article) is responsible for compliance of this substance. This includes the impurities of this substance and the expected reaction products it may form at this or a later manufacturing step under the specified use.

All aspects of compliance work linked to the introduction or generation of a substance may not be finalised at the manufacturing stage at which the substance is introduced. Therefore the DoC serves as means to inform on the aspects of compliance work that have been performed by the business operator issuing the DoC and which aspects still need to be performed by the downstream business operators. For example if migration of a substance cannot be predicted or measured at the stage of the polymer production, then the downstream business operator has to be informed that compliance work in relation to migration still needs to be performed. Such description of the compliance work must provide the customers with all information needed to perform this work.

4. Conclude compliance work as high up in the manufacturing chain as possible

Compliance work should be concluded as high up in the manufacturing chain as possible. As an example, in case of addition of a small quantity of a substance with a high SML, it may be possible at the plastic manufacturing stage to ensure compliance and conclude compliance work, e.g. based on the calculation that even with complete migration the SML would not be reached. However, in particular in multilayers, it has to be taken into account, that a substance can originate from several layers and compliance has to be ensured for the final article taking into account contribution from all layers.

5. Information from customer to supplier on intended use

Through communication between customer and supplier the customer may already provide necessary information to his supplier that will enable the supplier to complete the compliance work at his stage. For example if the plastic converter informs the plastic manufacturer on the exact shape or size, food contact conditions and contacting food of his final article the plastic manufacturer may already conclude the compliance work.

6. Specific description of compliance work transferred to the customer (see comment DD at the end of document)

The description of the compliance work that is transferred to the customer must be specific and allow him to perform the compliance work. It obliges the supplier to disclose the identity of substances and in some cases their concentration present in the material. Information passed from customer to supplier in the supply chain can help to identify relevant information that allows the supplier to adequately perform his compliance work. The customer is also obliged to critically assess the information provided by the supplier.

7. Responsibility of compliance work not transferred to the customer

A business operator automatically accepts responsibility for compliance work if he is not providing specific description of compliance work transferred to the customer.

3.

3. ROLES AND OBLIGATIONS IN THE SUPPLY CHAIN

The obligations on business operators in the context of the information in the supply chain depend on the following:

- the type of product being delivered to the direct customer (chemical substances, intermediate materials, final FCM or pre-packaged food)
- the role of the business operator
- the position of the business operator in the supply chain

These aspects will be explained below. Note that examples given below on types of materials and on processing or manufacturing operations are for clarification or illustration purposes and not intended to be exhaustive.

3.1. The type of product being delivered to the direct customer.

The following four cases can be distinguished, whether the product is:

a) a **chemical substance** e.g. a monomer or other starting substance including those covered by Article 6(3)(d) [2], additive, solvent, aid to polymerization, polymerization production aid or other processing aid, colorant, filler, etc. and mixtures obtained by mixing these substances without a chemical reaction of the components covered by Article 6(3)(b). In short this is any basic chemical ingredient to be used in the further manufacturing of materials which are further used in the manufacturing of plastic materials and articles intended for use in contact with food. However it does not include formulations or preparations as defined under b).

b) an "**intermediate plastic material**" which is referred to in Art. 15 as a "product from intermediate stages of manufacture" e.g. a plastic powder, granules or flakes (including "masterbatch[3]"), pre-polymer excluding Article 6(3)(d), any semi-finished material and article such as a film, sheet, laminate, etc. requiring further processing/re-formulation steps to become a "finished" material or article. In short this is any product which is not a basic chemical and not yet a finished plastic material or article. For the purpose of this document the plastic layers intended to be used in multi-material multilayers but not yet part of it are regarded as intermediate materials. A material or article which already has its final formulation[4] but still requires mechanical re-shaping under heat[5] to reach its final article shape, (e.g. thermo-formable sheets and bottle pre-forms) are regarded as intermediates. The reason is that the composition[6] may change due to reaction and degradation.

c) an "**intermediate non-plastic material**" is an ink, a coating or an adhesive formulation applied in the printing or coating of plastic articles or in combining of plastic layers. They still require application on the plastics and may require drying or curing. The composition may change due to reaction and degradation .

d) the **"final plastic material or article"** ready to go into contact with food[7] but not yet in contact with food. This can be:

   i. the finished plastic food contact material or article (e.g. packaging material, storage containers for food, bulk food or food ingredients, bottle, tray, kitchenware or utensil, plastic part in food-processing machinery, food preparation surface);

   ii. the plastic layers inside a finished multi-material multilayer;(see the box)

[2] when used as monomer or other starting substance, pre-polymers and natural or synthetic macromolecular substances, as well as their mixtures, except macromolecules obtained from microbial fermentation, if the monomers or starting substances required to synthesise them are included in the Union list. They have to be chemically characterized.

[3] a masterbatch is a plastic granule with a high concentration of additive and/or colourant, intended to be blended into other granules (not used to make an article as such)

[4] Formulation refers to intentionally added substances;

[5] Heat sealing is not covered by this term and the materials are considered as final articles before they are heat sealed.

[6] composition refers to substances actually present including reaction and degradation products

[7] including bulk food or food ingredients/intermediates

iii. finished components of the final food contact material or article which only need to be brought together or assembled, either during packing/filling or before, to make the final article (e.g. bottle and cap, tray and lid, parts of kitchenware or food processing machinery);

Finished multilayer articles

The final article coming into contact with food is the finished multi-material multilayer as a whole. However the whole multi-material multilayer is not regulated by Regulation (EU) No 10/2011. Specifically, Article 2 point 1(e) places "plastic layers in multi-material multi-layer materials and articles" in the scope of the Regulation. Article 3 point 1(b) defines that the plastic layers in multimaterial multi-layer materials and articles are "plastic materials and articles" in the context of the Regulation. Article 4 giving the requirements for placing on the market of plastic materials and articles, and Article 15 on Declaration of Compliance therefore relate only to the plastic layers in multi-material multilayers. For the purpose of this Regulation, the plastic layers in a multi-material multi-layer material and article, are legally treated as if they are the finished article even though physically they are not.

The consequence is that the operator placing the finished multi-material multi-layer on the market, has to issue a DoC that, legally in the context of Regulation (EU) No 10/2011, addresses the plastic layers in his product. In some countries, national legislation may require him to address also the non-plastic layers in his DoC. It should also be understood that the plastic layers intended for use in a multi-material multi-layer but not yet part of it, are considered intermediate materials. This would be relevant for the operators supplying to the manufacturer of the finished multi-material multi-layer.

In summary this is any material or article which is ready for food contact without any further change to the formulation of the material or article. The composition of the FCM may however still change due to degradation or the interaction with the food.

3.2. The role of the business operator

"Business operator" is defined in Article 2 of the Framework Regulation as "the natural or legal person(s) responsible for ensuring that the requirements of the Regulation are met within the business under their control".

It is important to look at the actions or activities the operator undertakes which are relevant in this context, and to then allocate one or more of the following roles to the operator which will subsequently define his obligations:

a) a "**substance manufacturer**" is any operator, who manufactures or produces a chemical substance as defined under 3.1.a).

b) a "**manufacturer of plastic intermediate materials**" is any operator who uses the chemical substances defined under 3.1.a) or mixtures of them and processes them into the intermediate products defined under 3.1.b). In this context, processing means any type of chemical reaction including polymerization, as well as physical processes e.g. blending, drying, mixing, etc. if it results into intermediate materials as described in 3.1.b). Also included here is the manufacturing of films, sheets, pre-forms etc which are not the final plastic material and article, by processes such as extrusion, lamination, injection moulding.

c) a "**manufacturer of non-plastic intermediate materials**" is any operator who uses the chemical substances defined under 3.1.a) or mixtures of them and processes them into the intermediate products defined under 3.1.c).

d) a "**manufacturer of final materials and articles**" is any operator who uses chemical substances defined under 3.1.a) and/or intermediate materials as defined under 3.1.b) and c), to manufacture final materials or articles as defined under 3.1.d). The manufacturing processes in this stage are very diverse and include chemical processes (e.g. mixing of reactive ingredients) as well as physical processes e.g. extrusion, laminating, blow-moulding, injection moulding, printing, coating, calendaring, thermoforming, stretch blow moulding.

e) a "**user of food contact materials and articles**" is any operator or person who puts food or food ingredients/intermediates in contact with a final material or article as defined under 3.1.d. This includes the food industry and their ingredient suppliers, retailers with an additional role of user, and food vendors (catering, restaurants, canteens, baker/butcher stores and other food outlets).

Included here are operators who carry out the operations described under 3.1.d. (iii) before or during putting the material or article in contact with food, as well as other processes needed for packing/filling,. Examples are e.g. sealing, coding, applying a label, capping a bottle, pasteurisation or sterilisation of the packed food, etc.

Users of food contact materials who sell food to consumers have an additional role as "retailer".

f) a "**distributor**" is any operator who supplies any of the products defined under 3.1.a),b),c),d) to a business operator without having manufactured the product himself. If the operator is selling to consumers, he has the role of a retailer instead. Distribution terminals of supermarkets and wholesale outlets are covered by the term retailers.

Depending on the country of origin of the products sold, the distributor may additionally have the role of importer (see next point).

When carrying out processes such as e.g. blending, mixing, printing, coating – any process affecting the formulation of the material or article – the operator has the role of a manufacturer. When carrying out the operations described under 3.1.d) without putting the food into contact with the material or article, the operator also has the role of manufacturer.

g) an "**importer**" is any business operator who releases or intends to release into free circulation in the EU goods defined under 3.1.a),b),c),d), from countries or territories not forming part of the customs territory of the EU. Purchasing from a representative of the third-country seller located within the customs territory of the EU, is not importing; instead the representative would be the importer.

Purchasing from a seller located in another country within the customs territory of the EU is not importing; instead the purchaser may have the role of a distributor or any other role, depending on his activities.

h) a "**retailer**" is a business operator selling final plastic materials and articles with or without food only to the final consumer. It includes distribution terminals of supermarkets and wholesale outlets. If the operator is selling to a business operator then he has the role of a distributor instead.

Retail as defined in the General food law (EC) 178/2002 Article 3(7)
'retail' means the handling and/or processing of food and its storage at the point of sale or delivery to the final consumer, and includes distribution terminals, catering operations, factory canteens, institutional catering, restaurants and other similar food service operations, shops, supermarket distribution centres and wholesale outlets;

Business operators that are retailers may have an additional role of "user of food contact materials or articles" if they put food in contact with materials or articles e.g. if they have in-house food preparation and/or packaging operations (either in a separate company location, or in a back room on the premises, or over-the-counter).

Business operators that are retailers may also be importers and would then have to fulfil the obligations of an importer.

i) A "**final consumer**" is not a business operator but a private person buying food or food contact materials and articles, or the two combined, from a retailer or "user". The consumer should follow the instructions of use.

The business operator finding himself in more than one role for a given product, should fulfil all the obligations resulting from each of the roles identified.

Examples for business operators having different roles

1. A soft drink producer

If he buys bottles, fills them with the soft drink and closes them with a closure his only role is that of user of a food contact materials.

If he buys bottle pre-forms which he blow-moulds into the final bottles, fills them with the soft drink and closes them with a closure his role is not only that of user of a food contact material but also that of the manufacturer of a final article. For the blow-moulding operation he has to fulfil the obligations of a manufacturer of a final article.

2. A catering business

A catering business is providing the food to the consumer and thus has the role of a retailer. He is preparing the food and is filling them into plastic boxes for transport and presentation to the consumer. This task defines him as a food packer and thus a user of food contact materials and he has to fulfil the obligations of a user of a food contact material.

3. A supermarket

A supermarket is selling freshly cut sausage in plastic trays that he has imported from a third country. He is providing the food to the consumer and is thus a retailer. He puts the sausage into contact with the plastic trays and is thus a user of food contact materials. He is importing the trays that he uses for that purpose and is thus an importer. He thus has three different roles and for each task he has to fulfil the respective obligations.

3.3. Obligations of the different operator roles

Article 15.1 of the Plastics Regulation sets out the general obligation: at all marketing stages of the supply chain other than at the retail stage the availability of a DoC is mandatory.

Furthermore, the supplier of intermediate materials which are not plastics but inks, coatings or adhesives, does not have to deliver a DoC but has to provide "adequate information" to his customer.

The DoC or the "adequate information" for non-plastic intermediate materials does not necessarily need to be physically attached to the goods, nor need it be sent out every time a customer receives a repeat order of the same goods. Instead it should be made available to the customer either in paper form or electronically or subject to the agreement of the customer via download from a website[8]. Any change in the legislation and/or in the substances or material composition or purity affecting the DoC delivered according to this chapter shall require an update of the DoC. The customer needs to be informed by the supplier about such updates. The customer does not have the legal obligation to ask for an update if the legislation changes, but it is good practice to do so.

When requested by the enforcement authorities the DoC or the "adequate information" should be made available to them without delay.

In point 4 of this guidance it will be explained further, which parts of the DoC as laid down in the Annex IV of the Plastics Regulation are relevant, as well as the details on the contents for each of those parts, dependent on the business operator's role.

Further obligations which cover information available in the supply chain are set out in the Framework Regulation (see box on link with the Framework Regulation and GMP). All these aspects are not treated in detail in this guidance, but sometimes may be referred to when considered relevant.

[8] The supplier needs to inform his customer on the website from which to download the document

Supporting documents

The provision to keep supporting documents (Article 15) applies to all stages of manufacture including retail and is not directly linked to the availability of a declaration of compliance. A declaration of compliance received from the supplier becomes a supporting document. In-house documentation on the in-house quality control becomes a supporting document. Results on migration testing performed in-house or by a contract laboratory become supporting documents.

Detailed obligations for each of the operator roles:

a) The "**manufacturer of substances**" is excluded from the scope of the GMP Regulation but should give information about the suitability of the substance(s) for food contact applications and provide a DoC in cases (i) to (iii) or 'adequate information' in case (iv) below.

A distinction needs to be made between the following situations:

(i) substances authorised and listed in Annex I of the Plastics Regulation and used to manufacture plastics;

(ii) substances exempt from authorisation and listing in the Plastics Regulation, but used to manufacture plastics covered by Article 6(1), (2), (3), (4)(b), (5);

(iii) substances intended to be used behind a functional barrier and thus exempt from authorisation and listing (Article 13(2)(b), 14(2))

(iv) substances being used to manufacture adhesives, coatings or inks.

The information requirements for these cases will be explained in point 4.2 of this document.

b) the "**manufacturer of plastic intermediate materials**" always has to provide a DoC to his direct customer. The information requirements for this case will be explained in point 4.3.1 of this document.

c) the "**manufacturer of non-plastic intermediate materials**" always has to provide "adequate information" to his direct customer. The information requirements for this case will be explained in point 4.3.2 of this document.

d) the "**manufacturer of final materials and articles**" always has to provide a DoC to his direct customer. The information requirements for these cases will be explained in point 4.4 of this document. An exception exists when the direct customer is a final consumer or a retailer not having another role (see 3.2.h). In this case, particular attention should be given to the labelling requirements of Art. 15(1)(b) of the Framework Regulation.

When a business operator is not only manufacturing the plastic food contact material but is also using it within its premises it is not necessary to issue a DoC (see example soft drink producer in box page X). However, supporting documents need to be kept by the business operator.

Labelling requirements Art.15 of (EC) 1935/2004

It is required that clear and easily understood instructions on the safe and appropriate use of the food contact material are given. This includes also clarification on any limitations of use. This information is to be given in accompanying documents (when provided to another business operator), on the labels or packaging or on the materials and articles themselves (when provided to the final consumer or business operator).

e) the "**user of food contact materials and articles**" that does not have the obligation to issue a DoC has to pay particular attention to instruct the consumer so that packaged food is handled safely and in an appropriate manner. This applies in particular to any limitations to the conditions of storage (temperature, contact time etc.) and, if relevant re-heating.

The 'user' has to keep "supporting documents" that contain information on compliance work performed and a suitable demonstration of the safety of the food contact material and article in

relation to the specific food for which it is used. It shall also address any relevant aspects of the operations carried out on the material or article before or during the packing/filling operation as mentioned under 3.2.d). In this context the possibility for generation of reaction or degradation products should be considered on the basis of the information provided by the supplier.

f) the "**distributor"** has to provide his direct customer with a DoC or "adequate information" depending on the product he sells (see previous points 3.2.a),b),c)). The information requirements for these cases are explained in points 4.2, 4.3. and 4.4 of this document. An exception applies if the customer is a retailer not having another role (see 3.2.g)). When this exception applies, particular attention should be given to the labelling requirements of Art. 15(1)(b) of the Framework Regulation. It is required that clear and easily understood instructions on the safe and appropriate use of the product are given. This includes also clarification on any limitations of use. For the DoC or the "adequate information" the distributor has the choice of either forwarding the supplier's document to his customer (with a cover sheet identifying his role in the supply chain), or else to issue his own, capturing the relevant information contained in his supplier's document.

g) the **"importer**" of substances, intermediates and materials not yet in contact with food, and selling his products to other business operators except retailers, always has to provide his direct customer with a DoC or "adequate information" depending on the product he imports (see previous points).

The "**importer**" of materials and articles not yet in contact with food, and selling his products (not yet in contact with food) to consumers or to retailers not having another role (see 3.2.g)), does not have to issue a DoC. In this case, particular attention should be given to the labelling requirements of Art. 15(1)(b) of the Framework Regulation.

The "**importer**" of materials and articles already in contact with food He should have "supporting documents" on the compliance of the material and article with EU food contact legislation and on the safety of the food itself, which he should be able to provide to competent authorities on request.

Declaration of compliance

The written declaration referred to in Article 15 shall contain the following information:

(1) the identity and address of the business operator issuing the declaration of compliance;

(2) the identity and address of the business operator which manufactures or imports the plastic materials or articles or products from intermediate stages of their manufacturing or the substances intended for the manufacturing of those materials and articles;

(3) the identity of the materials, the articles, products from intermediate stages of manufacture or the substances intended for the manufacturing of those materials and articles;

(4) the date of the declaration;

(5) confirmation that the plastic materials or articles, products from intermediate stages of manufacture or the substances meet relevant requirements laid down in this Regulation and Regulation (EC) No 1935/2004;

(6) adequate information relative to the substances used or products of degradation thereof for which restrictions and/or specifications are set out in Annexes I and II to this Regulation to allow the downstream business operators to ensure compliance with those restrictions;

(7) adequate information relative to the substances which are subject to a restriction in food, obtained by experimental data or theoretical calculation about the level of their specific migration and, where appropriate, purity criteria in accordance with Directives 2008/60/EC, 95/45/EC and 2008/84/EC to enable the user of these materials or articles to comply with the relevant EU provisions or, in their absence, with national provisions applicable to food;

(8) specifications on the use of the material or article, such as:

  (i) type or types of food with which it is intended to be put in contact;

  (ii) time and temperature of treatment and storage in contact with the food;

  (iii) ratio of food contact surface area to volume used to establish the compliance of the material or article;

(9) when a functional barrier is used in a multi-layer material or article, the confirmation that the material or article complies with the requirements of Article 13(2), (3) and (4) or Article 14(2) and (3) of this Regulation.

4. CONTENT OF THE DECLARATION OF COMPLIANCE AND "ADEQUATE INFORMATION" ALONG THE SUPPLY CHAIN

4.1. Aim of this chapter and general considerations

The aim of this chapter is to establish which information should be reported in the DoC or as "adequate information" for non-plastic materials so that the requirements set under the Plastics Regulation are met.

Any change in the legislation and/or in the substances or material composition or purity affecting the compliance statement delivered according to this chapter shall require an update of the DoC or the "adequate information" statement.

The identity of the business operator should be the officially registered name of the company.

The address of the business operator should be the physical address of the company; it can be supplemented by a website address. If the business operator who is issuing the DoC is the same as the business operator who is manufacturing or importing then point (1) and (2) of the DoC can be combined and filled in once.

Business operators issuing DoC which are not manufacturers

Sometimes a DoC is issued by other organisations such as

- Contract research laboratories
- Law firms
- Consultancies

In this case they have performed the compliance work on behalf of the manufacturer and are issuing the DoC on his behalf.

If several manufacturing operations are performed at different physical locations within EU territory of one company the DoC can be issued by a single responsible function on behalf of all company' manufacturing operations. Also in this case point (1) and (2) of the DoC can be combined and filled in once.

The numbers listed below for each DoC or "adequate information" refer to those aspects listed under the same numbers in Annex IV of the Plastics Regulation.

4.2. Manufacturers, distributors or importers of Substances

Business operators that are manufacturers, distributors or importers of substances should issue a DoC or "adequate information" if the substances are intended to be used in plastic food contact materials and articles.

4.2.1 Substances for the manufacture of Plastics

The DoC below reflects the information to be provided in case of single substances. For mixtures of substances relevant information concerning each substance of the mixture should be provided in the DoC. If the mixture contains substances of the both categories A) and B) below the relevant information under points A) and B) should be combined.

The following information should be reported:

A) DoC for substances authorised and listed in the Annex I of the Plastics Regulation and used to manufacture plastics

1. The identity and address of the business operator issuing the declaration of compliance
2. The identity and address of the business operator which manufactures or imports the substance

3. The identity of the substance: at least one of trade name, FCM Substance number, Ref number, CAS number or chemical name as listed in Annex I of the substance. In case of ***dual use additive*** the E-number of food additives or the FL number of flavourings should be reported as well.
   In case of substances with restrictions or when downstream user is informed that further specifications of use need to be established by downstream operators at least the FCM Substance number and optionally also CAS number, Ref number or chemical name as listed in Annex I should be provided.
4. The date of the declaration
5.
   a. Confirmation that the substance is authorised under the Plastics Regulation together with its use in the polymer (indicated in Annex I column 5 and 6: monomer, and/or additive and/or polymer production aid and supplemented with relevant information in Annex I column 10)
   b. Confirmation that the substance is of a technical quality and a purity suitable for the intended and foreseeable use and that impurities have been assessed in line with Article 19
6.
   a. Relevant restrictions as listed in Annex I and II such as SML, SML (T), ***QM*** or a confirmation that no restriction applies
   b. Confirmation that ***compositional or purity specifications*** as mentioned in column 10 of Annex I of the Plastics Regulation are met or that no specifications apply
7. In case of dual use additive(s), where appropriate, confirmation that the substance respects the purity criteria for food additives
8. Specification of use in relation to the final article as indicated in Annex I column 10. An indication if any other ***specification of use*** needs to be respected[9] or an indication that the downstream user needs to establish, if necessary, additional specifications of use.
   i. Specifications of use as regards ***type or types of food***
   ii. specification of time and temperature of treatment and storage with food
   iii. Any other limitations of use
9. Not relevant covered under point C)

Dual use additive

Covers a substance that is authorised as additive in plastics and at the same time authorised as food additive or flavouring.

A substance is defined "dual use additive" if the chemical identity of the plastic additive matches that of an authorised food additive or flavouring, regardless of its purity or whether or not the substance is subject to a restriction in food and/or in the plastic.

In the case of salts it is the salt that matters, not the authorised acid, phenol or alcohol.
Example: calcium stearate is a dual use additive (E470a) but zinc stearate is not. The substance listed in Regulation 10/2011 is stearic acid. Note that calcium stearate is identified as E470a even if the purity doesn't match that of its use in food.

The main intention of the legislation is that the user of food contact materials is informed on the presence of a dual use additive in the plastic so that these can be considered in relation to the relevant food legislation or interactions between food and packaging.

Examples of QM restrictions

- 1 mg/kg in final product
- 0,5% in final product

Examples of purity or compositional specifications

- Oxirane < 8 %
- iodine number < 6
- Average molecular weight not less than 440 Da.
- Viscosity at 100 °C not less than 3,8 cSt (3,8 x 10^{-6} m^2/s)
  According to the JECFA specifications, Purity ≥ 96 %

B) <u>DoC for substances exempt from authorisation and/or listing in the Plastics Regulation, but used to manufacture plastics covered by Article 6 (1),(2),(3),(4)(b),(5)</u>

1. The identity and address of the business operator issuing the declaration of compliance
2. The identity and address of the business operator which manufactures or imports the substance.
3. The identity of the substance: at least one of trade name, FCM Substance number, Ref number, CAS number or chemical name of the substance. In case of substances with restrictions in Annex I of the Plastics Regulation or under National legislation or when information on specification of use is delegated to the downstream user, CAS number, FCM Substance number, Ref number or

[9] At the substances stage specifications of use beyond those listed in the Regulation usually cannot yet be established and are therefore primary obligation at later stages of the manufacture. However, customer and supplier may agree on additional specifications of use that should be part of the DoC at this stage.

chemical name should be provided. In case of ***dual use additive*** the E-number of food additives or the FL number of flavourings should be reported as well.

4. The date of the declaration
5.
   a. One of the three below
      i. Confirmation that the substance is covered by the authorisation in the Plastics Regulation even if not explicitly listed in Annex I (Article 6 (3)) together with its use (indicated in Annex I column 5 and 6: monomer, and/or additive and/or polymer production aid, supplemented with relevant information in Annex I column 10[10]), the identity of the FCM substance number under which it is covered should be provided; for polymeric additives Article 6(3)(c) and pre-polymers covered by Article 6(3)(d) confirmation that all monomers are listed in Annex I and disclosure of the FCM numbers of the authorised monomers subject to a restriction should be provided.
      ii. Confirmation that the substance is authorised under national legislation, on food contact plastics (Article 6 (1), (2), (4)(b), (5)) together with its use.
      iii. Confirmation that the substance has been risk assessed in line with Article 19 (Article 6 (1), (2), (4)(b), (5)) or provide relevant information to support the risk assessment under Art 19 by the downstream user based on the conditions of use
   b. Confirmation that the substance is of a technical quality and a purity suitable for the intended and foreseeable use and that impurities have been assessed in line with Article 19 together with its use as monomer or other starting substance, additive or polymer production aid

Examples of specification of use of substances

- In case of use as a monomer only to be used as a co-monomer in aliphatic polyesters up to maximum level of 1 % on a molar basis;
- Only to be used in: (a) polyolefins at 0,1% (w/w) concentration and in (b) PET at 0,25% (w/w) concentration;
- Only to be used as a co-monomer for the preparation of polymeric additive

Examples of specification of use of materials

- Only in repeated use article
- For long term storage at room temperature

6.
   a. Relevant restrictions as listed in Annex I and II such as SML, SML(T), ***QM***[11] (relevant for substances 3.3.(a)i) or as listed in the National legislation (in this case reference the legislation) or a confirmation that no restrictions apply
   b. Confirmation that the ***compositional or purity specifications*** [12]as mentioned in column 10 of Annex I (relevant for substances 3. 3.(a)i) of the Plastics Regulation or as mentioned in the National legislation (in this case reference the legislation) are met or a confirmation that no specifications apply
7. In case of ***dual use additive***(s), where appropriate confirmation that the substance respects the purity criteria of food additives
8. ***Specification of use***[13] in relation to the final article or an indication if any other specification of use needs to be respected or an indication that the downstream user needs to establish, if necessary, additional specifications of use.
   a. Specifications of use as regards type or ***types of food***[14] indicated in Annex I column 10
   b. Specification of time and temperature of treatment and storage with food in Annex I column 10
   c. Any other limitations of use

Examples of Types of food

- Not to be used for articles in contact with fatty foods for which simulant D is laid down
- Only to be used in hydrogels intended for non-direct food contact use
- For indirect food contact only, behind a PET layer
- For materials and articles intended for contact with aqueous foods only

[10] see box on Examples of specifications of use of substance
[11] See box on Examples of QM restrictions
[12] See box on Purity or compositional specifications
[13] See box on Examples of specification of use of materials
[14] See box on examples of types of foods

9. Not relevant

C**) <u>DoC for substances intended to be used behind a functional barrier and thus exempt from authorisation and listing covered by Article 13(2)(b)[15], 14(2)</u>**

1. The identity and address of the business operator issuing the declaration of compliance
2. The identity and address of the business operator which manufactures or imports the substance.
3. The identity of the substance: chemical name of the substance or CAS number.
4. The date of the declaration
5.
   a. Confirmation that the substance does not meet the criteria for classification as "mutagenic", "carcinogenic" or "toxic to reproduction" in accordance with the criteria set out in sections 3.5, 3.6. and 3.7 of Annex I to CLP Regulation (EC) No 1272/2008 of the European Parliament and the Council
   b. Confirmation that the substance is not in nanoform as defined by Commission Recommendation of 18 October 2011 on the definition of nanomaterial (2011/696/EU)[16]
6. not applicable
7. not applicable
8. not applicable
9. Information that the substance can only be used behind a functional barrier and that the migration of the substances into food or food simulant shall not be detectable with a limit of detection of 0,01mg/kg

4.2.2 Substances for the manufacture of non-plastic intermediates: adhesives, coatings or printing inks

<u>"Adequate information" for substances listed in Annex I or II with an SML or SML(T) being used to manufacture adhesives, coatings or printing inks</u>

For substances being used to manufacture intermediate materials other than plastics, the legal requirements on a declaration of compliance for plastics at EU level are not applicable.

The obligation to issue "adequate information" covers not only substances listed in Annex I or II with an SML or SML(T) but also substances of the following categories:

- salts of authorised acids, phenols or alcohols subject to Article 6(3)(a),
- mixtures subject to Article 6(3)(b),
- polymeric additives subject to Article 6(3)(c),
- polymeric starting substances subject to Article 6(3)(d)

if restrictions for the linked substances are listed in Annex I or II.

The following information should be reported:

1. The identity and address of the business operator responsible for issuing the "adequate information"
2. Not relevant.
3. The identity of the substance: CAS number, FCM Substance number, Ref number or chemical name should be provided. In case of ***dual use additive***[17] the E-number of food additives or the FL number of flavourings should be reported. In case of substances covered by Article 6(3) the identity of the substance for which the restriction is established.

DoC in national legislation

A DoC may be required by national legislation. In any case, certain information has to be provided in the supply chain so that the operator incorporating these products into a plastic material or article can issue a correct declaration of compliance for his product. The use of these substances shall comply with the general requirements in Article 3 of the Framework Regulation.

[15] substances listed in 13(2)(a) are covered by A)
[16] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:275:0038:0040:EN:PDF
[17] See box on dual use additives

4. The date of the document
5. Confirmation that the substance is authorised under the Plastics Regulation
6. Relevant restrictions as listed in Annex I and II such as SML, SML (T), ***QM*** [18]
7. Not applicable
8. Information to support the risk assessments under Article 19 to be performed by downstream users based on the conditions of use.
   If appropriate indication of type or ***types of food*** [19]or ***specification of time and temperature of treatment and storage with food***[20].
9. Not relevant

4.3. Manufacturers, distributors or importers of Intermediate Materials

4.3.1. Manufacturers, distributors or importers of plastic Intermediate Materials

DoC for a Plastic Intermediate Material including plastic layers intended to be used in a multi-material multilayer but not yet part of it

1. The identity and address of the business operator issuing the declaration of compliance
2. The identity and address of the business operator which manufactures or imports the plastic intermediate materials.
3. The identity of the plastic intermediate material (trade name and ***polymer type***[21])
4. The date of the declaration
5. Confirmation that the plastic intermediate material complies with relevant requirements of the Framework Regulation as described below:
   a. Confirmation that the intermediate is manufactured only with monomers, other starting substances and additives that are authorised under the Plastics Regulation[22]
   b. Confirmation that intentionally added substances not subject to listing in Annex I comply with the relevant requirements of the Framework Regulation and that a risk assessment in accordance with Article 19 has been performed. If further steps of the risk assessment in accordance with Article 19 have to be performed by the downstream operator the identity of the substance (chemical name and CAS number) together with relevant information for the risk assessment has to be provided[23].
   c. Confirmation that reaction intermediates, decomposition or reaction products comply with the relevant requirements of the Framework Regulation and that a risk assessment in accordance with Article 19 has been performed. If further steps of the risk assessment in accordance with Article 19 have to be performed by the downstream operator the identity of the substance (chemical name and CAS number) together with relevant information for the risk assessment has to be provided[24].

Examples of polymer types

- High Density Polyethylene (HDPE)
- Low Density Polyethylene (LDPE
- Linear Low Density Polyethylene (LLDPE)
- Polypropylene (PP)
- Polystyrene (PS)
- Expandable polystyrene (EPS)
- Polyethyleneterephthalate (PET)
- Ethylene Vinyl Alcohol copolymers (EVOH)
- Polyamide (PA)
- Polyvinylchloride (PVC)

[18] See box on QM
[19] See box on types of food
[20] See box on specification of use of materials
[21] See box on Examples of polymer types
[22] For plastics intended to be used behind a functional barrier point 5a is not relevant
[23] Relevant information is the amount of substance present or adequate information that allows the exposure assessment, it can also include toxicological information about the substance
[24] Relevant information is the amount of substance present or adequate information that allows the exposure assessment, it can also include toxicological information about the substance

6. Information on substances with restrictions in Annex I or II[25] of Regulation 10/2011 and on intentionally added substances that are subject to restrictions in National Legislation (EU + EEA Countries)[26]
   a. For substances that are subject to restrictions in national legislation only, the applicable national legislation should be referenced[27]
   b. Identity of the substances (FCM substance number, Ref number, CAS number or chemical name). In the following cases disclosure of the identity is not mandatory if the customer is informed on the presence of non-disclosed substances[28]:
      i. The business operator confirms that the substance is not migrating in detectable concentrations, with indication of the detection limit[29], if the material is used under the conditions of use explicitly specified in the DoC under point 8
      ii. The business operator confirms that **the restriction** cannot be exceeded up to a certain material layer thickness or concentration of material in a blend, provided the conditions of use for which compliance is tested are clearly specified under point 8
      ALTERNATIVE
      The business operator confirms that **one tenth of the restriction** cannot be exceeded up to a given material layer thickness or concentration of material in a blend, provided the conditions of use for which compliance is calculated or tested are clearly specified under point 8
      iii. The business operator confirms that the residual concentration is so low that one tenth of the restriction is not exceeded on the basis of worst case calculation or modelling or migration data.

      Sub-paragraphs i, ii and iii can be refined based on the appropriate level of communication between the business operator and customer, allowing the latter to prove on the basis of the information received on the other materials supplied from the same or other suppliers that the SML cannot be exceeded (Examples are given at the end of the document).
   c. Restriction of the substances (SML, SML(T) ***QM***)[30] or confirmation that no substances with restrictions in Annex I are used
   d. In case that substances listed in Annex II (1) are present a confirmation that these substances cannot be released above the limit specified or an indication for the downstream operator to check for the substance/s that are indicated
   e. In case that the plastic materials and articles could release PAAs covered by Annex II (2) or that substances are present that can generate PAAs covered by Annex II (2) a confirmation that the PAAs cannot be released above the detection limit. Alternatively the downstream operator is informed which PAAs must be checked.
   f. In case that further steps of the compliance work need to be performed by the downstream operator the identity of the substance (chemical name and CAS number) together with relevant information has to be provided
7. Information on ***dual use additives***
   Identity of substance as listed in the European legislation on additives or flavourings, ((EC) n° 1333/2008, 1334/2008) (Substance name and E-number or FL number)
8. Information related to the final use of the material or article, especially any restrictions or limitations applicable on the ***conditions of use***, in particular those that result from the restrictions and/or specifications indicated in Annex I column 10 on the substances used.

[25] For plastics intended to be used in a multi-material multilayer this information should also be provided
[26] National legislation needs to be checked for manufacturers in that Member State and importers from third countries. For plastics in multi-material multilayers national legislation needs to be checked for applicable requirements on multi-material multilayers.
[27] This covers colorants, polymer production aids, substances on the provisional list, aids to polymerisation
[28] In view of transparent communication in the supply chain the non-disclosure should be the exception
[29] The detection limits can be an experimental value or a threshold used from modelling or worst case calculation
[30] Even in cases were the identity of a substance is not disclosed the restriction of the substance has to be indicated. E.g. By mentioning a none-disclosed substance is present with a migration limit of 0.05 mg/kg.

a. Specifications of use as regards type or ***types of food*** indicated in Annex I column 10
b. Specification of time and temperature of treatment and storage with food
c. Ratio of food contact ***surface area to volume ratio***

9. For plastics to be used behind a functional barrier
   a. The indication that the material can only be used behind a functional barrier
   b. A confirmation that the non authorised additives and monomers present
      i. does not meet the criteria for classification as "mutagenic", "carcinogenic" or "toxic to reproduction" in accordance with the criteria set out in sections 3.5, 3.6. and 3.7 of Annex I to CLP Regulation (EC) No 1272/2008 of the European Parliament and the Council
      ii. are not in nanoform as defined by Commission Recommendation of 18 October 2011 on the definition of nanomaterial (2011/696/EU)[31]
   c. An indication of suitable materials and the conditions under which the materials work as a functional barrier for the substance in question.
      If such an indication cannot be given the identity of the substances (chemical name or CAS number) has to be provided to allow the downstream user to establish the functional barrier and verify that migration is not detectable

Examples for ratio of food contact surface area to volume ratio

- up to a surface to volume ratio of 6 dm2/kg
- suitable for surface volume ratio of up to x dm2/kg

(based on the conventional assumption that 1l equals 1kg usually the surface to weight ratio is indicated)

4.3.2. Manufacturers, distributors or importers of non-plastic Intermediate Materials

"Adequate Information" for a Non-Plastic Intermediate (inks, adhesives, coatings)

1. The identity and address of the business operator which is responsible for issuing the "adequate information"
2. Not relevant
3. The identity of the non-plastic intermediate material.
4. The date of the document
5. Confirmation that the intermediate material complies with relevant requirements of the Framework Regulation[32] and will allow the final plastic material or article to comply with the Framework Regulation when used under GMP and in accordance with the information communicated by the supplier of the intermediate material.[33]
6. Information on substances with restrictions in Annex I or II of Regulation 10/2011 and on intentionally added substances that are subject to restrictions in National Legislation (EU + EEA Countries)[34]
   a. For substances that are subject to restrictions in national legislation only, the applicable national legislation should be referenced
   b. Identity of the substances (FCM substance number, Ref number, CAS number or chemical name). In the following cases disclosure of the identity is not mandatory if the customer is informed on the presence of non-disclosed substances:

Information exchange for non-plastic intermediates to be used behind functional barriers

After an exchange of information between supplier and customer following information should be provided: either an indication of suitable materials and the conditions under which the materials work as a functional barrier for the substance in question, or confirmation that the material selected as barrier layer would be a suitable functional barrier that ensures that the migration (including set-off) is within acceptable limits. If such an indication cannot be given the information in points 1-8 should be provided.

[31] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:275:0038:0040:EN:PDF
[32] Relevant requirements of the Framework Regulation are GMP and traceability
[33] If the Non-Plastic Intermediate Material is marketed in a Member State where it is subject to National Legislation (EU + EEA Countries) the applicable national legislation should be referenced and compliance with the relevant National Legislation should be confirmed including information on restrictions or specifications, if applicable.
[34] National legislation needs to be checked for manufacturers in that Member State and importers from third countries. -.

i. The business operator confirms that the substance is not migrating in detectable concentrations, with indication of the detection limit[35], if the material is used under the conditions of use explicitly specified
ii. The business operator confirms that the restriction cannot be exceeded, provided the conditions of use for which compliance is confirmed are clearly specified

c. Restriction of the substances (SML, SML(T) ***QM***)[36]
d. In case that substances listed in Annex II (1) are present a confirmation that these substances cannot be released above the limit specified or an indication for the downstream operator to check for the substance/s that are indicated
e. In case that the plastic materials and articles could release PAAs covered by Annex II (2) or that substances are present that can generate PAAs covered by Annex II (2) a confirmation that the PAAs cannot be released above the detection limit. Alternatively the downstream operator is informed which PAAs must be checked.
f. In case that further steps of the compliance work need to be performed by the downstream operator the identity of the substance (chemical name and CAS number) together with relevant information has to be provided

7. Information on ***dual use additives*** present in the Non-Plastic Intermediate Material: Identity of substance as listed in the European legislation on additives or flavourings, ((EC) n° 1333/2008, 1334/2008) (Substance name and E-number or FL number)
8. Information to support the risk assessments under Article 19 to be performed by downstream users based on the conditions of use. If appropriate indication of type or types of food or specification of time and temperature of treatment and storage with food or the necessity of a functional barrier.
9. Not applicable

Why no DoC for non-plastics intermediates?

The Plastics Regulation does not set out an obligation to issue a DoC for the non-plastics parts of a plastic material or article. However, as the Plastics Regulation requires that migration of authorised substances and certain other substances should not exceed the established migration limits it is necessary that "Adequate Information" is provided by the manufacturers of adhesives, printing inks and coatings that allows the manufacturer of the final plastic article to establish compliance with the Plastics Regulation for these substances.

4.4. Manufacturers, distributors or importers[37] of Final Materials and Articles

Final materials and articles that are covered in this section are plastic materials and articles defined in the scope of the Plastics Regulation Article 2(1). Section 4.4.A explains the requirements on a DoC for plastic materials and articles covered under Article 2(1) points (a), (b), (c) and (d). Section 4.4.B explains the requirements on a DoC for the plastic layers inside a finished multi-material multilayer as covered under Article 2(1) point (e). For multi-material multilayers as a whole no requirements exist at EU level to issue a DoC.[38]

A) Information to be provided for a plastic Final Material or Article

1. The identity and address of the business operator issuing the declaration of compliance
2. The identity and address of the business operator which manufactures or imports the plastic material or article.
3. The identity of the plastic material or article (trade name & ***material types***[39])

[35] The detection limits can be an experimental value or a threshold used from modelling or worst case calculation
[36] Even in cases were the identity of a substance is not disclosed the restriction of the substance has to be indicated. E.g. By mentioning a none-disclosed substance is present with a migration limit of 0.05 mg/kg.
[37] See section 3.3 points (f) and (g) for clarification in which cases a distributer or importer has the obligation to issue a DoC.
[38] Check national legislation for national requirements to issue a DoC for multi-material multilayers.
[39] For plastics this is the polymer type; additionally the presence of adhesives, coatings or inks should be indicated.

4. The date of the declaration
5. Confirmation that the plastic material or article complies with relevant requirements of the Framework Regulation and the Plastics Regulation as follows:
    a. Confirmation that the plastics which are not separated from the food by a functional barrier are manufactured only with monomers, other starting substances and additives that are authorised under the Plastics Regulation.
    b. Confirmation that substances intentionally added to plastics, not subject to listing in Annex I[40] comply with the relevant requirements of the Framework Regulation and that a risk assessment in accordance with Article 19 has been performed. If it is necessary for the final user to perform further steps of the risk assessment in accordance with Article 19, the identity of the substance (chemical name and CAS number) together with relevant information[41] for the risk assessment must be provided.
    c. Confirmation that reaction intermediates, decomposition or reaction products in plastics comply with the relevant requirements of the Framework Regulation and that a risk assessment in accordance with Article 19 has been performed. If it is necessary for the final user to perform further steps of the risk assessment in accordance with Article 19, the identity of the substance (chemical name and CAS number) together with relevant information[42] for the risk assessment must be provided.
    d. Confirmation that the FCM complies with the OML, and details on the test conditions used in this assessment and/or the OM Test Number according to Table 3 of Annex V of the Plastics Regulation, including the simulant(s) used.
    e. Confirmation that FCM sold directly to consumer complies with organoleptic requirements
6. Information on substances with restrictions in Annex I or II and on intentionally added substances that are subject to restrictions in National Legislation (EU + EEA Countries)
    a. In case only national legislation applies, the applicable national legislation should be referenced[43].

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    b. Identity of the substances used (FCM substance number, Ref number, CAS number or chemical name). Disclosure of the identity is not mandatory[44] if the customer is informed on the presence of non-disclosed substances and the business operator has confirmed that the substance is not migrating above the migration limit if the material is used under the conditions of use specified under point 8.
    c. Restriction of the substances used or (SML, SML(T) or ***QM***)[45] or confirmation that no substances with restrictions in Annex I
    d. In case that substances listed in Annex II (1) are present a confirmation that these substances cannot be released above the limit specified or an indication for the downstream operator to check for the substance/s that are indicated
    e. In case that the plastic materials and articles could release PAAs covered by Annex II (2) or that substances are present that can generate PAAs covered by Annex II (2) a confirmation that the PAAs cannot be released above the detection limit. Alternatively the downstream operator is informed which PAAs must be checked.

Articles to be assembled by the user (e.g. bottle and lids)
In this context it may be necessary that the identity of a restricted substance is provided even if each article for itself is respecting the relevant restriction. This would be the case if the customer reports back that the unidentified substance has the same restriction as another substance in his assembled article.

[40] Substances referred to in Articles 6(1), 6(2), 6(4), 6(5) and 14(2)
[41] Relevant information is the amount of substance present or adequate information that allows the exposure assessment, it can also include toxicological information about the substance
[42] Relevant information is the amount of substance present or adequate information that allows the exposure assessment, it can also include toxicological information about the substance
[43] This covers colorants, polymer production aids, substances on the provisional list, aids to polymerisation
[44] This does not preclude the business operator to identify all restricted substances in the context of the level of service provided within the business relationship with the customer.
[45] Even in cases were the identity of a substance is not disclosed the restriction of the substance has to be indicated, e.g. by mentioning “a non-disclosed substance is present with a migration limit of 0.05 mg/kg”.

f. Confirmation that the restrictions mentioned in point c), d), e) are complied with. If it is necessary for the user of the final article to carry out further steps of the compliance assessment, the identity of the substance (FCM substance number, Ref number, CAS number or chemical name) together with relevant information[46] for the compliance assessment has to be provided.

ALTERNATIVE B

b. Identity of the substances used in plastics (FCM substance number, Ref number, CAS number or chemical name). Disclosure of the identity is not mandatory[47] if the customer is informed on the presence of non-disclosed substances and the business operator has confirmed that the substance is not migrating above the migration limit if the material is used under the conditions of use specified under point 8.
c. Restriction of the substances in plastics (SML, SML(T) or ***QM***)[48] or confirmation that no substances with restrictions in Annex I
d. In case that substances listed in Annex II (1) are present a confirmation that these substances cannot be released above the limit specified or an indication for the downstream operator to check for the substance/s that are indicated
e. In case that the plastic materials and articles could release PAAs covered by Annex II (2) or that substances are present that can generate PAAs covered by Annex II (2) a confirmation that the PAAs cannot be released above the detection limit. Alternatively the downstream operator is informed which PAAs must be checked.
f. Confirmation that the restrictions mentioned in point c), d), e) are complied with. If it is necessary for the user of the final article to carry out further steps of the compliance assessment, the identity of the substance (FCM substance number, Ref number, CAS number or chemical name) together with relevant information[49] for the compliance assessment has to be provided.
g. If relevant, confirmation that the compliance of substances used in inks, coatings or adhesives – that are also listed with a restriction in Annex I or II of the Plastics Regulation – has been assessed. If it is necessary for the user of the final article to carry out further steps of the compliance assessment, the identity of the substance (FCM substance number, Ref number, CAS number or chemical name) together with relevant information for the compliance assessment has to be provided.

Articles to be assembled by the user (e.g. bottle and lids)
In this context it may be necessary that the identity of a restricted substance is provided even if each article for itself is respecting the relevant restriction. This would be the case if the customer reports back that the unidentified substance has the same restriction as another substance in his assembled article.

7. Information on ***dual use additives***: Identity of substance as listed in the European legislation on additives or flavourings, ((EC) n° 1333/2008, 1334/2008) (Substance name and E-number or FL-number)[50]
8. Information related to the ***final use*** of the material or article, especially any restrictions or limitations applicable on the conditions of use, in particular those that result from the results and test conditions for the OML compliance as well as the restrictions and/or specifications indicated in Annex I column 10 on the substances used.
    a. Specifications of use as regards type or ***types of food*** indicated in Annex I column 10;
    b. Specification of time and temperature of treatment and storage with food;
    c. Ratio of food contact ***surface area to volume*** or weight of food, used to establish the compliance.

[46] Relevant information is the amount of substance present or adequate information that allows the exposure assessment, it can also include toxicological information about the substance
[47] This does not preclude the business operator to identify all restricted substances in the context of the level of service provided within the business relationship with the customer.
[48] Even in cases were the identity of a substance is not disclosed the restriction of the substance has to be indicated, e.g. by mentioning "a non-disclosed substance is present with a migration limit of 0.05 mg/kg".
[49] Relevant information is the amount of substance present or adequate information that allows the exposure assessment, it can also include toxicological information about the substance
[50] Information on amount migrating or residual concentration to be indicated to the customer on request

9. For final materials and articles containing plastic layers behind a functional barrier the DoC should contain
    a. confirmation that the non authorised additives and monomers present
        i. do not meet the criteria for classification as "mutagenic", "carcinogenic" or "toxic to reproduction" in accordance with the criteria set out in sections 3.5, 3.6. and 3.7 of Annex I to CLP Regulation (EC) No 1272/2008 of the European Parliament and the Council
        ii. are not in nanoform as defined by Commission Recommendation of 18 October 2011 on the definition of nanomaterial (2011/696/EU)[51]
    b. confirmation that under the intended condition of use the migration of the non-authorised additives and monomers into food or food simulant are not detectable with a limit of detection of 0,01mg/kg.
    If such an indication cannot be given under the actual conditions of use, the identity of the substances (chemical name and/or CAS number) has to be provided as well as any other information needed to allow the food business operator to establish the functional barrier and verify that migration is not detectable.

B) Information to be provided for the plastic layer(s) in a finished multi-material multilayer (MMML).

1. The identity and address of the business operator issuing the declaration of compliance
2. The identity and address of the business operator which manufactures or imports the MMML.
3. The identity of the plastic material or article (trade name & description of the composition)
4. The date of the declaration
5. Confirmation that the plastic layer of the MMML complies with relevant requirements of the Framework Regulation and the Plastics Regulation as follows:
    a. Confirmation that the plastic layers of the MMML which are not separated from the food by a functional barrier are manufactured only with monomers, other starting substances and additives that are authorised under the Plastics Regulation.
    b. Confirmation that intentionally added substances[52] in the plastic layers of the MMML, comply with the relevant requirements of the Framework Regulation and that a risk assessment in accordance with Article 19 has been performed[53]. If it is necessary for the user of the final article to carry out further steps of the risk assessment in accordance with Article 19, the identity of the substance (chemical name and CAS number) together with relevant information[54] for the risk assessment has to be provided.
    c. Confirmation that reaction intermediates, decomposition or reaction products in the plastic layers of the MMML comply with the relevant requirements of the Framework Regulation and that a risk assessment in accordance with Article 19 has been performed. If it is necessary for the user of the final article to carry out further steps of the risk assessment in accordance with Article 19, the identity of the substance (chemical name and CAS number) together with relevant information for the risk assessment has to be provided.
6. If relevant, confirmation that the MMML complies with the restriction on vinylchloride monomer (FCM substance No 127, migration not detectable with detection limit of 0,01 mg/kg food, residual content 1 mg/kg plastic).
7. Information on ***dual use additives***: Identity of substance as listed in the European legislation on additives or flavourings, ((EC) n° 1333/2008, 1334/2008) (Substance name and E-number or FL-number)

[51] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:275:0038:0040:EN:PDF
[52] This includes all intentionally added substances also monomers, other starting substances and additives.
[53] If for substances listed with a restriction in the Plastics Regulation, the method chosen to demonstrate compliance with the Framework Regulation is based on the SML as if the FCM was a plastic, then that information may also be reported under point 6.
[54] Relevant information is the amount of substance present or adequate information that allows the exposure assessment, it can also include toxicological information about the substance

8. Information related to the ***final use*** of the material or article, especially any restrictions or limitations applicable on the conditions of use, including the restrictions and/or specifications on the plastic layers of the MMML as indicated in Annex I column 10.
9. For final materials and articles containing plastic layers behind a functional barrier the DoC should contain
    a. confirmation that the non authorised additives and monomers present
        i. do not meet the criteria for classification as "mutagenic", "carcinogenic" or "toxic to reproduction" in accordance with the criteria set out in sections 3.5, 3.6. and 3.7 of Annex I to CLP Regulation (EC) No 1272/2008 of the European Parliament and the Council
        ii. are not in nanoform as defined by Commission Recommendation of 18 October 2011 on the definition of nanomaterial (2011/696/EU)[55]
    b. confirmation that under the intended condition of use the migration of the non-authorised additives and monomers into food or food simulant are not detectable with a limit of detection of 0,01mg/kg.
    If such an indication cannot be given under the actual conditions of use, the identity of the substances (chemical name and/or CAS number) has to be provided as well as any other information needed to allow the food business operator to establish the functional barrier and verify that migration is not detectable.

[55] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:275:0038:0040:EN:PDF

Examples illustrating SECTION 4.3.1. POINT 6.

Example 1:
A film manufacturer produces a 3 layers film (PP/PE/PP).
The polypropylene grade (the two PP layers are manufactured from the same PP grade supplied by the same supplier) does not contain any additive with SML. The PE supplier does not want to disclose, the additive with an SML of x mg/kg present in the PE grade sold, but confirms that the SML will not be exceeded by worst case calculation (100 % migration) for a film thickness of 150 µ. The customer will be able to confirm compliance with this respect as the thickness of the PE layer is 150µ or less. If the customer wants to use it above 150 µ then additional communication with the supplier is necessary

Example 2:
Same example as above, but now the PP supplier is confirming the use of an additive with an SML y mg/kg.
The customer can confirm compliance as he has the proof that the two additives with SML used by his two suppliers are different.

Example 3:
Same Example as 1, but this time the PE and PP suppliers have both indicated the same SML of x mg/kg for their respective additive. It may or may not be the same additive. In that case the two suppliers will have to disclose a maximum level for the additive present. With that information, the customer can check compliance as a worst case scenario (same additive, both levels added together). If by calculation the SML is exceeded, then additional communication with the supplier is necessary to receive more detailed information.