



Brussels, 28.11.2013

Union Guidance on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food as regards information in the supply chain

This document is presenting the outcome of discussion in a working group of technical experts and the working group of governmental experts on food contact materials.

This guidance was presented to and endorsed by the Member States in the Standing Committee section Toxicological Safety on the Food Chain of 28 November 2013.

The guidance is aimed at European Professional Organisations and Member States competent authorities dealing with questions concerning the interpretation and implementation of certain aspects on the declaration of compliance and adequate information in the plastics supply chain. This document is an evolving document and will be updated to further clarify aspects related to the implementation of this legislation.

This document is made available on the DG Sanco website on food contact materials:
http://ec.europa.eu/food/food/chemicalsafety/foodcontact/documents_en.htm

Disclaimer: This document, drawn up by the services of the Directorate-General for Health and Consumers, is not binding on the European Commission as an Institution. Please note that this document cannot provide a formal interpretation of European Union law in relation to specific situations. It does also not provide legal advice on issues of national law.

For questions to this document, please contact SANCO-FCM@ec.europa.eu

Contents

<u>1</u>	<u>INTRODUCTION</u>	<u>3</u>
<u>2</u>	<u>AIM OF THE DOC.....</u>	<u>4</u>
<u>3</u>	<u>ROLES AND OBLIGATIONS IN THE SUPPLY CHAIN</u>	<u>8</u>
3.1	THE TYPE OF PRODUCT BEING DELIVERED TO THE DIRECT CUSTOMER.....	8
3.2	THE ROLE OF THE BUSINESS OPERATOR	9
3.3	OBLIGATIONS OF THE DIFFERENT OPERATOR ROLES	11
<u>4</u>	<u>CONTENT OF THE DECLARATION OF COMPLIANCE AND "ADEQUATE INFORMATION" ALONG THE SUPPLY CHAIN.....</u>	<u>14</u>
4.1	AIM OF THIS CHAPTER AND GENERAL CONSIDERATIONS	15
4.2	MANUFACTURERS, DISTRIBUTORS OR IMPORTERS OF SUBSTANCES	15
4.2.1	SUBSTANCES FOR THE MANUFACTURE OF PLASTICS.....	15
4.2.2	SUBSTANCES FOR THE MANUFACTURE OF NON-PLASTIC INTERMEDIATES: ADHESIVES, COATINGS OR PRINTING INKS	19
4.3	MANUFACTURERS, DISTRIBUTORS OR IMPORTERS OF INTERMEDIATE MATERIALS.....	20
4.3.1	MANUFACTURERS, DISTRIBUTORS OR IMPORTERS OF PLASTIC INTERMEDIATE MATERIALS	20
4.3.2	MANUFACTURERS, DISTRIBUTORS OR IMPORTERS OF NON-PLASTIC INTERMEDIATE MATERIALS.....	22
4.4	MANUFACTURERS, DISTRIBUTORS OR IMPORTERS OF FINAL MATERIALS AND ARTICLES	23
<u>5</u>	<u>ANNEX I.....</u>	<u>27</u>
5.1	EXAMPLES ILLUSTRATING SECTION 4.3.1. POINT 6 OF THE GUIDANCE DOCUMENT	27
<u>6</u>	<u>ANNEX I.....</u>	<u>28</u>
6.1	TABLE 1 – BUSINESS OPERATORS AND THEIR ROLES.....	28
6.2	TABLE 2 – BUSINESS OPERATORS AND THEIR OBLIGATIONS IN RELATION TO DOC, SUPPORTING DOCUMENTS AND LABELLING.....	29
<u>7</u>	<u>ABBREVIATIONS</u>	<u>31</u>
<u>8</u>	<u>REFERENCED LEGISLATION HYPERLINKS.....</u>	<u>32</u>

1 Introduction

This Guidance document is part of a series of documents to provide guidance on application of Regulation (EU) No 10/2011¹ on plastic materials and articles intended to come into contact with food (the "Plastics Regulation"). The series covers general guidance, guidance on migration testing, guidance on migration modelling and the present guidance on information in the supply chain.

This Guidance document covers information to be generated and exchanged in the supply chain, as required in the context of compliance with the Plastics Regulation.

Specifically, this Guidance document addresses:

- the aim of the Declaration of Compliance ("DoC");
- the DoC for plastic materials and articles, products from intermediate stage of their manufacturing and substances intended for the manufacturing of those materials and articles – set out in Article 15 and Annex IV of the Plastics Regulation;
- Adequate information on coatings, adhesives and inks ('non-plastic intermediates') which become part of plastic materials and articles (hereinafter "Adequate Information"). Recital 30 of the "Plastics Regulation" explains the reasoning behind the "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 this Regulation." The Guidance document therefore contains recommendations for this information to be provided, even if it has not been harmonised at EU level.

Why is there no requirement for a 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 considered necessary that Adequate Information is provided by the manufacturers of adhesives, printing inks and coatings that will allow the manufacturer of the final plastic article to establish compliance with the Plastics Regulation for these substances. This Guidance document is recommending that manufacturers of adhesives, printing inks and coatings provide to their customers Adequate Information. This Guidance document gives recommendations on the content of such Adequate Information.

This Guidance document also explains the link of the DoC with the Regulation (EC) No 1935/2004² on materials and articles intended to come into contact with food (the "Framework Regulation") and Regulation (EC) No 2023/2006³ on good manufacturing practice for materials and articles intended to come into contact with food (the "GMP Regulation").

This Guidance document is based on the current understanding of the Commission Services on the availability of a DoC at all marketing stages, except the retail stage, as provided for in Article 15(1) of the Plastics Regulation. The Guidance document will be updated in case the provisions of the Plastics Regulation are amended, in order to improve clarity, consistency and applicability.

It should be noted that this Guidance document does not elaborate on the DoC for materials and articles already in contact with food, such as packaging.

Where appropriate, this Guidance document mentions certain aspects related to supporting documents, to the labelling provisions of the Framework Regulation or to documentation requirements under the GMP. However, it does not aspire to cover these topics in depth (See box on [page 6](#)). The competent authorities of Member States can also request documentation on the food contact material of packaged food based on Article 10 of Regulation (EC) No 882/2004⁴ on official controls to ensure the verification of compliance with

¹ Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food (OJ L 12, 15.1.2011, p. 1).

feed and food law (the "Control Regulation"). Certain Member States have set out national requirements for the DoC for other materials. These are not subject of this Guidance document, but need to be respected in cases where national law is applicable.

2 Aim of the DoC

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

The DoC is a document delivered by the supplier to his customer at marketing stages up to but excluding the retailer. 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 to establish or check the compliance of the product with relevant legislation.

In order to allow the exchange of relevant information, the information to be included in the DoC is set out in a standard format in Annex IV of the Plastics Regulation. This Guidance document contains details on information to be provided at the different manufacturing and marketing stages of plastics to fulfil the requirements of the Plastics Regulation.

It is recommended that the DoC and the Adequate Information are issued in one or more EU languages that are easily understood both by the supplier and by the customer. The information given has to be clear and distinct. Information should relate to the actual composition of the material. Several materials with different composition leading to significant differences in reportable substances cannot be covered by one DoC. On request by enforcement authorities, the DoC should be made available to them without delay. Language requirements set out in national measures implementing official controls should be respected.

One DoC can cover a number of variations of a material or article which differ in their size, shape, thickness or colour or in the source of supply of one or a few of the components, leading to a limited number of variations in the reportable substances, provided that all reportable substances are listed. In this case, the compliance assessment has to cover all the variations. The document has to identify the articles of a product family it is covering and also indicate on which product the DoC is based. Supporting documents need to be available to provide reasoning for the choice. Differences in reportable substances due to variations in supply sources have to be identified e.g. through asterisk at the respective substances. Further information on the reportable substances of the individual material or article has to be made available to the customer and the competent authorities on request. Information given should not be misleading or inconclusive. A similar approach is recommended for the Adequate Information.

If a general disclaimer is included in the DoC, this cannot invalidate the statements of compliance 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 intended to be passed along the supply chain but

² Regulation (EC) No 1935/2004 of the European Parliament and of the Council on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4).

³ Commission Regulation (EC) No 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food (OJ L 384, 29.12.2006, p. 75).

⁴ 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 (OJ L 191, 28.5.2004, p. 1).

should be made available to the competent authorities on request. The DoC which the business operator receives from the supplier will become part of his [compliance work](#), together with other information, such as test results generated for this product.

The manufacturer of the final plastic material or article has to issue a DoC for his product, which 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 recommended 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 document gives recommendations on the information considered adequate to 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 documents. [Compliance work](#) covers a risk assessment, including 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 Section 3 of this Guidance document. Section 4 of this Guidance document explains which information needs to be provided in the DoC based on the position of the business operator in the supply chain.

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 non-intentionally added substances such as impurities and degradation products, plastic processing conditions, composition of the food, storage and contact conditions, among others, 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 include all the information contained in the supplier's [Supporting Documents](#).

Examples for supporting documents

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

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

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

Labelling requirements (Article 15 of the 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 of the 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 easily 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 does not induce an **unacceptable change** in the **composition of the food** or cause a deterioration in the **organoleptic properties of the food**;
- that the labelling, advertising and presentation of a material or article does not mislead the consumers.

Stating compliance with Good Manufacturing Practice (GMP)

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

- that a **quality assurance system** is established covering, amongst others,
 - 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 control system** is established.

Information on the selection criteria applied to starting materials (such as identity, purity, toxicological profile) is particularly relevant for substances not subject to authorisation and listing in Annex I to the Plastics Regulation. 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

Producers performing the same compliance work on the same material should be avoided. 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 the possibility 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 the substance and degradation and/or decomposition products linked to its intended use which may be formed 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 or Adequate Information serves as means to inform on the aspects of compliance work that have been performed by the business operator issuing the DoC or Adequate Information and on which aspects still need to be performed by the downstream business operators.

4. Conclude compliance work as early as possible in the manufacturing chain

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 that part of the 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 this 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 relevant aspects of the compliance work.

6. Specific description of compliance work transferred to the customer

The description of the compliance work that is transferred to the customer must be specific and allow him to perform the compliance work. There are some cases which oblige the supplier to disclose the identity of substances and it may be also necessary to disclose their concentration 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 a specific description of compliance work transferred to the customer.

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; and,
- the position of the business operator in the supply chain

These aspects will be explained below. Note that the examples given below on types of materials and on processing or manufacturing operations are for clarification or illustration purposes and are 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) of the Plastics Regulation⁵, 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) of the Plastics Regulation. 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 point b) below.
- b) an **“intermediate plastic material”** which is referred to in Article 15 of the Plastics Regulation as a “product from intermediate stages of manufacture” e.g. a plastic powder, granules or flakes (including “masterbatch⁶”), pre-polymer excluding Article 6(3)(d) of the Plastics Regulation, 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 formulation⁷, but still requires mechanical re-shaping under heat⁸ to reach its final article shape, (e.g. thermo-formable sheets and bottle pre-forms) is regarded as an intermediate material. The reason is that the composition⁹ 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 food¹⁰, but not yet in contact with food. This can be:

⁵ 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.

⁶ Masterbatch means a preparation of one or more polymers which encapsulate a high concentration of ingredients like colorants, fillers, fibres, stabilizers etc. that influence the physical properties of the final preparation. A masterbatch is intended to be blended with a polymer and not used to make an article as such.

⁷ Formulation refers to intentionally added substances.

⁸ Heat sealing is not covered by this term and the materials are considered as final articles before they are heat sealed.

⁹ Composition refers to substances actually present including reaction and degradation products.

¹⁰ Including bulk food or food ingredients/intermediates.

- 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 below);
- 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).

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.

Finished multi-material multilayer articles ("MMML")

The final article coming into contact with food is the finished MMML as a whole, including plastic and non-plastic layers. However, the whole MMML is not regulated by the Plastics Regulation. Specifically, the scope of the Plastics Regulation only covers **plastic layers** in MMML (Article 2 point 1(e)). **Plastic layers** in MMML are defined as "plastic materials and articles" in the context of the Plastics Regulation (Article 3, point 1(b)). The requirements for placing on the market of plastic materials and articles are set out in Article 4 of the Plastics Regulation. The DoC, therefore, relates only to the plastic layers of the MMML. For the purpose of the Plastics Regulation, the plastic layers in a MMML, are legally treated as if they are the finished article, even though physically they are not.

In consequence, the operator placing the finished MMML on the market has to issue a DoC that, legally in the context of the Plastics Regulation, addresses **only the plastic layers** in the product.

In some Member States, national legislation may require the operator to address also the non-plastic layers in his DoC. It should also be understood that the plastic layers intended for use in a MMML but not yet part of it, are considered intermediate materials. This is relevant for the operators supplying to the manufacturer of the finished MMML.

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 point 3.1.a) of this Guidance document.
- b) A “**manufacturer of plastic intermediate materials**” is any operator who uses the [chemical substances](#) defined under point 3.1.a) of this Guidance document or mixtures of them and processes them into the [intermediate products](#) defined under point 3.1.b) of this Guidance document. 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 point 3.1.b) of this Guidance document. Also included here is the manufacturing of films, sheets, laminate, 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) of this Guidance document or mixtures of them and processes them into the [intermediate products](#) defined under point 3.1.c) of this Guidance document.
- d) A “**manufacturer of final materials and articles**” is any operator who uses [chemical substances](#) defined under point 3.1.a) of this Guidance document and/or intermediate materials as defined under points [3.1.b\)](#) and [c\)](#) of this Guidance document, to manufacture [final materials or articles](#) as defined

under point 3.1.d) of this Guidance document. 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, and 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 point 3.1.d) of this Guidance document. 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 point [3.1.d\)\(iii\)](#) of this Guidance document 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 "retailers".

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 point [3.1.d\)\(iii\)](#) of this Guidance document without putting the food into contact with the material or article, the operator also has the role of manufacturer.

- f) A “**distributor**” is any operator who supplies any of the products defined under points [3.1.a\),b\),c\),or d\)](#) of this Guidance document 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).

- g) An “**importer**” is any business operator who releases or intends to release into free circulation in the EU goods defined under points [3.1.a\),b\),c\)](#), or [d\)](#) of this Guidance document, from countries or territories not forming part of the customs territory of the EU¹¹. 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 Regulation (EC) No 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.

¹¹ Covers EU, EEA countries and all countries for which a customs union is established for FCM.

Business operators that are retailers may have an additional role of “users 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 as packaged foods, 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 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 in addition.

3. A supermarket

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

If the supermarket prints the expiration date on the plastic trays it would also have to fulfil the obligations of a manufacturer.

3.3 Obligations of the different operator roles

Article 15(1) of the Plastics Regulation sets out the general obligation that 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 (unless required by national legislation, since there is no harmonised requirement at EU level), but is recommended to provide Adequate Information to his customer.

The DoC 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 website¹². Relevant changes in the legislation and/or any change 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. It is recommended that the same approach is applied to the Adequate Information for non-plastic intermediate materials.

When requested by the enforcement authorities, the DoC should be made available to them without delay.

In Section 4 of this Guidance document, it will be explained further which parts of the DoC, as laid down in 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 Article 15 of the [Framework Regulation](#). All these aspects are not treated in detail in this Guidance document, but sometimes may be referred to when considered relevant.

Supporting documents

The provision to keep supporting documents (Article 16 of the Plastics Regulation) applies to all stages of manufacture and marketing, including retail, and is not directly linked to the availability of a DoC. A DoC 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.

Supporting documents should also address any relevant aspects of the operations carried out on the material or article before or during the packing/filling operation. In this context, the possibility for generation of reaction or degradation products should be considered on the basis

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 issue and provide a DoC in cases (i) to (iii) below or is recommended to issue and provide 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 exempted from authorisation and listing in the Plastics Regulation, but used to manufacture plastics covered by Article 6(1), (2), (3), (4)(b), or (5) of the Plastics Regulation;
- (iii) substances intended to be used behind a functional barrier and thus exempted from authorisation and listing covered by Article 13(2)(b) or 14(2) of the Plastics Regulation, and
- (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 Guidance document.

- b) the **“manufacturer of plastic intermediate materials”** always has to issue and provide a DoC to his direct customer. The information requirements for this case will be explained in point 4.3.1 of this Guidance document.
- c) the **“manufacturer of non-plastic intermediate materials”** is recommended to always issue and provide Adequate Information to his direct customer. The recommended information for this case will be explained in point 4.3.2 of this Guidance document.

¹² The supplier needs to inform his customer on the website from which to download the document

- d) the **“manufacturer of final materials and articles”** always has to issue and provide a DoC to his direct customer. The information requirements for these cases will be explained in point 4.4 of this Guidance document. An exception exists when the direct customer is a final consumer or a retailer not having another role (see 3.2.h) of this Guidance document). 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 between different premises of the business operator (see the example of the soft drink producer in [box page 11](#)). However, [supporting documents](#) need to be kept by the business operator.

Labelling requirements in Article 15 of the Framework Regulation

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 foreseeable 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) **“user of food contact materials and articles”** has to pay particular attention to instruct the consumer via adequate labelling, 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, to 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. (see also [box on page 12](#))

- f) the **“distributor”** has to issue and provide his direct customer with a DoC and is recommended to issue and provide Adequate Information depending on the product he sells (see points 3.2.a),b), and c) of this Guidance document). The information requirements for these cases are explained in points 4.2, 4.3 and 4.4 of this Guidance document. An exception applies if the customer is a retailer not having another role (see point 3.2.h) of this Guidance document). When this exception applies, particular attention should be given to the labelling requirements of Article 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 document, 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 issue and provide his direct customer with a DoC and is recommended to issue and provide Adequate Information depending on the product he imports.

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

Declaration of compliance (DoC)

The written declaration referred to in Article 15 of the Plastics Regulation shall contain the following information (Annex IV):

- (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.*

*The Directives are replaced by Regulations (EC) No 1333/2008 and (EC) No 1334/2008

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, so that the requirements set under the Plastics Regulation are met, or is recommended to be provided in the Adequate Information for non-plastic materials.

Any change in the legislation and/or in the substances or material composition or purity affecting the compliance statement delivered according to this chapter requires an update of the DoC and is recommended to be reflected in the Adequate Information for non-plastic materials.

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

The address of the business operator in the DoC 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, if this is clear on the document.

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.

Business operators involved in DoC work which are not manufacturers or importers

In some cases, other organisations than the manufacturer or importer perform compliance work on his behalf such as:

- Contract research laboratories
- Law firms
- Consultancies

In this case, they have performed the compliance work with regard to Annex IV to the Plastics Regulation on behalf of the manufacturer. However, it is still the manufacturer who has to issue the DoC.

Distributors are business operators that, in certain cases, have to issue a DoC, even if they are not the manufacturers or importers.

The numbers listed below for each DoC refer to those aspects listed under the same numbers in Annex IV to the Plastics Regulation. It is recommended to follow the same order in case of Adequate Information.

4.2 Manufacturers, distributors or importers of Substances

Business operators that are [manufacturers](#), [distributors](#) or [importers](#) of substances should issue and provide a DoC if the substances are intended to be used in plastic food contact materials and articles. Business operators that are [manufacturers](#), [distributors](#) or [importers](#) of substances used in adhesives, printing inks or coatings intended to be used in plastic food contact materials and articles are recommended to issue and provide Adequate Information for substances covered by the Plastics Regulation.

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 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 the following information should be provided: trade name, FCM Substance number, Reference number, CAS number or chemical name of the substance, as listed in Table 1 of Annex I of the Plastics Regulation (the "Union List"). In case of **dual use additive(s)**, either the E-number of food additives or the FL number of flavourings should be reported as well. In case of substances subject to restrictions included in Annex I to the Plastics Regulation or when the downstream operator is informed that further specifications of use need to be established by the downstream operators, at least the FCM Substance number and optionally also CAS number, Reference number or chemical name as listed in the Union List should be provided.
4. [The date](#) of the declaration.
5. [5.](#)
 - a. Confirmation that the substance is authorised under the Plastics Regulation, together with its use in the polymer (indicated in column 5 and 6 of the Union List: monomer, and/or additive and/or polymer production aid) and supplemented with relevant information in column 10 of the Union list).
 - b. Confirmation that the substance is of a technical quality and purity suitable for the intended and foreseeable use and that impurities have been assessed in line with Article 19 of the Plastics Regulation or that information is provided to the downstream user that is adequate to assess its suitability for its intended use.
6. [6.](#)
 - a. Relevant restrictions as listed in Annex I and II of the Plastics Regulation, 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 the Union List 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 column 10 of the Union List. An indication of whether any other **specification of use** needs to be respected¹³ or an indication that the downstream user needs to establish, if necessary, additional specifications of use.

Dual use additive

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

A substance is defined as "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 the Plastics Regulation 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 ($3,8 \times 10^{-6} \text{ m}^2/\text{s}$) According to the JECFA specifications, Purity $\geq 96 \%$.

¹³ At the substances stage, specifications of use beyond those listed in the Plastics 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.

- 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).

B) DoC for substances covered by Articles 6 (1),(2),(3),(4)(b), and (5) of the Plastics Regulation not included in the Union list, but 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 the following information should be provided: trade name, FCM Substance number, Reference number, CAS number or chemical name of the substance.

In case of substances subject to restrictions included in the Union List or under national legislation¹⁴ or when the downstream operator is informed that further specifications of use need to be established by the downstream operators, at least one of the following should be provided:

CAS number, FCM Substance number, Reference number or chemical name.

In the case of *dual use additive(s)*, either the E-number of food additives or the FL number of flavourings should be reported as well.

4. The date of the declaration.

5. 5.

- a. One of the three particulars below

- i. For substances covered by Article 6(3) of the Plastics Regulation:

Confirmation that the substance, together with its use (indicated in column 5 and 6 of the Union List): monomer, and/or additive and/or polymer production aid, supplemented with relevant information in column 10 of the Union List¹⁵) is covered by the authorisation in the "Plastics Regulation" (even if not explicitly listed in the Union List).

In addition the identity of the FCM substance number under which it is covered should be provided.

In particular for polymeric additives covered by Article 6(3)(c) and pre-polymers covered by Article 6(3)(d) a, confirmation that all monomers to produce the substances are listed in the Union List needs to be provided and the FCM numbers of the authorised monomers subject to a restriction should be disclosed.

- ii. For substances covered by Article 6 (1), (2), (4)(b), or (5) of the Plastics Regulation
A confirmation should be provided that the substance is authorised under national legislation, together with its use. The national legislation should be referenced. Or alternatively:

- iii. For substances covered by Article 6 (1), (2), (4)(b), or (5) of the Plastics Regulation:

A confirmation should be provided that the substance has been risk assessed in line with Article 19 of the Plastics Regulation or relevant information should be provided to support the risk assessment under Article 19 of the Plastics Regulation by the downstream operator 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

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.

¹⁴ National legislation in EU Member States or EEA countries, as appropriate.

¹⁵ See box on Examples of specifications of use of substance on this page

in line with Article 19 of the Plastics Regulation or information is provided to the downstream user that is adequate to assess its suitability for its intended use as monomer or other starting substance, additive or polymer production aid.

6. 6.
 - a. Relevant restrictions as listed in Annex I and II of the Plastics Regulation, such as SML, SML(T), QM¹⁶ (relevant for substances referred to under point 3.3.(a)i) of this Guidance document: covered by a listing in the Union List) or as listed in the national legislation (in this case, make reference to the legislation) or a confirmation that no restrictions apply.
 - b. Confirmation that the compositional or purity specifications¹⁷ as mentioned in column 10 of the Union List (relevant for substances referred to in point 3.3.(a)i) of this Guidance document) or as mentioned in the national legislation (in this case, make reference to 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 use¹⁸ 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 food¹⁹ indicated in column 10 of the Union List.
 - b. Specification of time and temperature of treatment and storage with food in column 10 of the Union List.
 - c. Any other limitations of use.
 9. Not relevant.
- C) DoC for substances covered by Articles 13(2)(b)²⁰ or 14(2) of the Plastics Regulation that are intended to be used behind a functional barrier and thus exempted from authorisation and inclusion in the Union list**
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. 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 Regulation (EC) No 1272/2008²¹ on classification, labelling and packaging of substances and mixtures (the "CLP Regulation").
 - 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)²² (the "Nanomaterial Recommendation").

Examples of restrictions regarding food types

- 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.

¹⁶ See box on [Examples of QM restrictions](#).

¹⁷ See box on [Purity or compositional specifications](#).

¹⁸ See box on [Examples of specification of use of materials](#).

¹⁹ See box on [Examples of types of foods](#).

²⁰ Substances listed in 13(2)(a) of the Plastics Regulation are covered by point A) above.

²¹ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, OJ L 353, 31.12.2008, p.1.

²² Commission Recommendation of 18 October 2011 on the definition of nanomaterial (2011/696/EU), OJL 275, 20.10.2011, p.38.

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

Recommendation for Adequate information for substances listed in Annex I or II of the Plastics Regulation with an SML or SML(T) being used to manufacture adhesives, coatings or printing inks

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

It is however recommended that Adequate Information is issued and provided that covers the substances listed in Annex I or II to the Plastics Regulation with an SML or SML(T) and substances of the following categories:

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

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

The following information is considered adequate to inform on substances with restrictions in the final plastic material or article:

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, Reference number or chemical name should be provided. In case of [dual use additive](#)²³, the E-number of food additives or the FL number of flavourings should be reported. In case of substances covered by Article 6(3) of the Plastics Regulation, the identity of the substance for which the restriction is established should be provided.
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 to the Plastics Regulation such as SML, SML (T), [QM](#)²⁴.
7. [Not applicable.](#)
8. Information to support the risk assessments under Article 19 of the Plastics Regulation to be performed by downstream users based on the conditions of use. If appropriate, indication of type or [types of food](#)²⁵ or [specification of time and temperature of treatment and storage with food](#)²⁶.
9. [Not relevant.](#)

DoC in national legislation for adhesives, coatings and printing inks

A DoC may be required by national legislation. In any case, certain information should 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.

²³ See box on [Dual use additives](#).

²⁴ See box on [Examples of QM restrictions](#).

²⁵ See box on [Examples types of food](#).

²⁶ See box on [Examples specification of use of materials](#).

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 MMML, 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](#)²⁷).
4. The [date of the declaration](#).
5. [Confirmation](#) that the [plastic intermediate material](#) complies with relevant requirements of the Plastics Regulation and the Framework Regulation, as described below:
 - a. Confirmation that the intermediate material is manufactured only with monomers, other starting substances and additives that are authorised under the Plastics Regulation²⁸.
 - b. Confirmation that intentionally added substances not subject to listing in the Union List comply with the relevant requirements of the Framework Regulation and that a risk assessment in accordance with Article 19 of the Plastics Regulation has been performed. If further steps of the risk assessment in accordance with Article 19 of the Plastics Regulation 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 provided²⁹.
 - 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 of the Plastics Regulation has been performed. If further steps of the risk assessment in accordance with Article 19 of the Plastics Regulation 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 provided³⁰.
6. [Information on substances with restrictions](#) in Annex I or II³¹ to the Plastics Regulation and on intentionally added substances that are subject to restrictions in national legislation^{32,33}.
 - a. For substances that are subject to restrictions in national legislation, only, the applicable national legislation should be referenced³⁴.
 - b. Identity of the substances (at least one of the following: FCM substance number, Reference number, CAS number or chemical name) should be provided. In the following cases, only

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)

²⁷ See box on [Examples of polymer types](#).

²⁸ For plastics intended to be used behind a functional barrier point 5a of the DoC is not relevant.

²⁹ 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.

³⁰ 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.

³¹ For plastics intended to be used in a multi-material multilayer this information should also be provided.

³² National legislation in EU Member States or EEA countries, as applicable.

³³ National legislation needs to be checked. For plastics in MMML, national legislation needs to be checked for applicable requirements on MMML.

³⁴ This covers colorants, polymer production aids, substances on the provisional list..

disclosure of the identity of a substance in the DoC is not mandatory if the customer is informed on the presence of non-disclosed substances³⁵:

- i. The business operator confirms that the substance is not migrating in detectable concentrations, with indication of the detection limit³⁶, if the material is used under the conditions of use explicitly specified in the DoC under point 8.
- ii. The business operator confirms that one tenth of the restriction³⁷ 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*) or confirmation that no substances with restrictions in Annex I to the Plastics Regulation are used. This information is mandatory even if non-disclosure of identity of substances in point (6)b.(i) to (iii) above applies.³⁸ If the substance has a unique SML and its disclosure means disclosure of confidential information, at least the existence of the restriction for the substance needs to be confirmed³⁹.
 - d. In case that substances listed in point 1. of Annex II to the Plastics Regulation 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 Primary Aromatic Amines (PAAs) covered by point 2. of Annex II to the Plastics Regulation or that substances are present that can generate PAAs covered by point 2. of Annex II to the Plastics Regulation, 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 (substance name and E-number or FL number) as listed in the European legislation on additives or flavourings, (Regulation (EC) No 1333/2008⁴⁰ on food additives, or Regulation (EC) No 1334/2008⁴¹ on flavourings).

³⁵ In view of transparent communication in the supply chain, the non-disclosure of the identity of a substance in the DoC should be the exception and disclosure of its identity should be agreed between business operators.

³⁶ The detection limits can be an experimental value or a threshold used from modelling or worst case calculation. The detection limit of the analytical method has to be below the applicable restriction of the given substance.

³⁷ Derived from the assumption that up to 10 layers containing the same substance could be combined in a material.

³⁸ Even in cases where 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".

³⁹ In view of transparent communication in the supply chain the non-disclosure of the identity of a substance in the DoC should be the exception and disclosure of its identity should be agreed between business operators.

⁴⁰ Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives, (OJ L 354, 31.12.2008, p.16).

⁴¹ Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC, (OJ L 354, 31.12.2008, p.34).

8. [Information related to the final use](#) of the material or article.

Identify especially any restrictions or limitations applicable on the [conditions of use](#), in particular those that result from the restrictions and/or specifications on the substances used indicated in column 10 of the Union List.

- a. Specifications of use as regards type or [types of food](#) indicated in column 10 of the Union List..
 - 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-listed 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 the CLP Regulation .
 - ii. are not in nanoform as defined by the Nanomaterial Recommendation.
 - 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](#)

Recommendation for Adequate Information for a Non-Plastic Intermediate Material (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 Regulation⁴² 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.⁴³
6. [Information](#) on substances with restrictions in Annex I or II of the Plastics Regulation and on intentionally added substances that are subject to restrictions in national legislation⁴⁴.
 - a. Reference of applicable national legislation for substances that are subject to restrictions in national legislation only.
 - b. Identity of the substances (at least one of the following: FCM substance number, Reference number, CAS number or chemical name). In the following cases, when the identity of a substance

⁴² Relevant requirements of the Framework Regulation are GMP and traceability.

⁴³ If the Non-Plastic Intermediate Material is marketed in a Member State where it is subject to national legislation (EU + EEA Countries), a reference to the applicable national legislation and confirmation of compliance with the relevant national legislation including information on restrictions or specifications, if applicable, is recommended.

⁴⁴ It is recommended that national legislation is checked for manufacturers in that Member State and importers from third countries.

in the Adequate Information is not disclosed, it is recommended that the customer is informed at least on the presence of non-disclosed substances⁴⁵:

- i. The business operator confirms that the substance is not migrating in detectable concentrations, with indication of the detection limit⁴⁶, 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) *OM*). This information is recommended, even if non-disclosure of identity of substances in point (6)b. (i) and (ii) above applies. If the substance has a unique SML and its disclosure means disclosure of confidential information, it is recommended that at least the existence of the restriction for the substance is confirmed.
 - d. In case that substances listed in Annex II (1) to the Plastics Regulation 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) to the Plastics Regulation or that substances that can generate PAAs covered by Annex II (2) to the Plastics Regulation are present, 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, (Regulation (EC) No 1333/2008, Regulation (EC) No 1334/2008) (Substance name and E-number or FL number).
 8. [Information](#) to support the risk assessments under Article 19 of the Plastics Regulation 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](#).

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

The following information is considered relevant:

- an indication of suitable materials and the conditions under which the materials work as a functional barrier for the substance in question,
- 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, or
- information in points 1-8.

4.4 [Manufacturers, distributors or importers](#)⁴⁷ 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 Article 2(1) of the Plastics Regulation. Section 4.4.A of this Guidance document explains the requirements on a DoC for plastic materials and articles covered under Article 2(1) points (a), (b), (c) and (d) of the Plastics Regulation. Section 4.4.B of this Guidance document explains the requirements on a DoC for the plastic layers inside a [finished MMML](#) as covered under Article 2(1) point (e) of the Plastics Regulation. There is no requirement to issue a DoC for the entire MMML.⁴⁸

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

⁴⁵ In view of transparent communication in the supply chain, the non-disclosure of the identity of a substance in the Adequate Information should be the exception and it is recommended that disclosure of its identity is agreed between business operators.

⁴⁶ The detection limits can be an experimental value or a threshold used from modelling or worst case calculation.

⁴⁷ See section 3.3 points (f) and (g) of this Guidance document for clarification on the cases in which a distributor or importer has the obligation to issue a DoC.

⁴⁸ Check national legislation for national requirements to issue a DoC for multi-material multilayers.

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*⁴⁹).
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 the Union List⁵⁰ comply with the relevant requirements of the Framework Regulation and that a risk assessment in accordance with Article 19 of the Plastics Regulation has been performed. If the risk assessment in accordance with Article 19 Plastics Regulation has not been completed in the previous stages, the identity of the substance (chemical name and CAS number), together with relevant information⁵¹ 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 of the Plastics Regulation has been performed. If the risk assessment in accordance with Article 19 of the Plastics Regulation has not been completed in the previous stages, the identity of the substance (chemical name and CAS number), together with relevant information⁵² for the risk assessment must be provided.
 - d. Confirmation that the FCM complies with the OML. This may be supplemented by details on the test conditions used in this assessment and/or the OM Test Number according to Table 3 of Annex V to the Plastics Regulation, including the simulatant(s) used.
 - e. Confirmation that FCM not yet in contact with food and intended for direct use by consumers complies with organoleptic requirements..
6. Information on substances with restrictions in Annex I or II of the Plastics Regulation and on intentionally added substances that are subject to restrictions in national legislation⁵³
 - a. In case only national legislation applies, the applicable national legislation should be referenced⁵⁴.
 - b. Identity of the substances used in plastics (at least one of the following FCM substance number, Reference number, CAS number or chemical name). Disclosure of the identity of a substance in the DoC is not mandatory⁵⁵ 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.

Assembled Articles

When users bring together two or more items of FCM into a single finished article, in some cases, additional steps in the compliance assessment have to be undertaken by the user assembling the finished article. This case can occur when compliance of specific migration limits are expressed differently for the finished article (e.g. bottle and lid). Additional information on non-identified substances may need to be requested from the supplier.

⁴⁹ For plastics, this is the [polymer type](#); additionally the presence of adhesives, coatings or inks should be indicated.

⁵⁰ Substances referred to in Articles 6(1), 6(2), 6(4), 6(5), 13(2)(b) and 14(2) of the Plastics Regulation.

⁵¹ Relevant information is the amount of substance present or adequate information that allows the exposure assessment, and it can also include toxicological information about the substance.

⁵² 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.

⁵³ National legislation in EU Member States or EEA countries, as applicable.

⁵⁴ This covers colorants, polymer production aids, substances on the provisional list, and aids to polymerisation

⁵⁵ In view of transparent communication in the supply chain, the non-disclosure of the identity of a substance in the DoC should be the exception and the disclosure of its identity should be agreed between business operators.

- c. Restriction of the substances in plastics (SML, SML(T) or [OM](#))⁵⁶ or confirmation that no substances with restrictions in Annex I to the Plastics Regulation.
 - d. In case that substances listed in Annex II (1) to the Plastics Regulation 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) to the Plastics Regulation or that substances are present that can generate PAAs covered by Annex II (2) to the Plastics Regulation, 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), and 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, Reference number, CAS number or chemical name), together with relevant information⁵⁷ for the compliance assessment has to be provided. (see also [Box on assembled articles](#)).
 - 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 (at least one of the following FCM substance number, Reference number, CAS number or chemical name) together with relevant information for the compliance assessment has to be provided.
7. [Information](#) on [dual use additives](#): Identity of substance as listed in the European legislation on additives or flavourings, (Regulation (EC) No 1333/2008, Regulation (EC) No 1334/2008) (Substance name and E-number or FL-number)⁵⁸.
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 column 10 of the Union List on the substances used.
- a. Specifications of use as regards type or [types of food](#) indicated in column 10 of the Union List.
 - 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.
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 the CLP Regulation.
 - ii. are not in nanoform as defined by the Nanomaterial Recommendation.
 - 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.

⁵⁶Even 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”.

⁵⁷Relevant information is the amount of substance present or adequate information that allows the exposure assessment and it can also include toxicological information about the substance.

⁵⁸Information on amount migrating or residual concentration to be indicated to the customer on request.

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 & [polymer type](#)).
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:
 - 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 substances⁵⁹ 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 of the Plastics Regulation has been performed⁶⁰. 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 of the Plastics Regulation, the identity of the substance (chemical name and CAS number), together with relevant information⁶¹ 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 of the Plastics Regulation 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 of the Plastics Regulation, 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 European legislation on additives or flavourings, (Regulation (EC) No 1333/2008, Regulation (EC) No 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](#), including the restrictions and/or specifications on the plastic layers of the MMML as indicated in column 10 of the Union List.
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 the CLP Regulation .
 - ii. are not in nanoform as defined by the Nanomaterial Recommendation.
 - b. Confirmation that, under the intended condition of use, the migration of the non-authorised additives and monomers into food or food simulant is 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.

⁵⁹ This includes all intentionally added substances and also monomers, other starting substances and additives.

⁶⁰ 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 of the DoC.

⁶¹ Relevant information is the amount of substance present or adequate information that allows the exposure assessment, and it can also include toxicological information about the substance.

5 Annex I

5.1 Examples illustrating SECTION 4.3.1. POINT 6 of the Guidance Document

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 μm at a given surface to volume ratio. The customer will be able to confirm compliance with this respect, as the thickness of the PE layer is 150 μm or less at the given or lower surface to volume ratio. If the customer wants to use it above 150 μm then additional communication with the supplier is necessary

Example 2:

Same Example as 1, 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.

6 Annex I

6.1 Table 1 – Business operators and their roles

Role	Examples	Action	Goods
Plastic Manufacturer	Chemical industry, plastic producers, plastic converters	Produce goods	Substance Intermediate Article
Non-plastic manufacturer	Chemical industry, producers of printing inks, adhesives, coatings	Produce goods	Substance Intermediate
Distributor	Distribution centres for chemicals, intermediates, final articles excluding food retailers distribution centres	Provide goods to business operator	Substance Intermediate Article
User	Food industry, caterers, restaurants, food business operators	Package, process, store food	Article
Retailer and their distribution centres	Supermarkets and food business operators selling directly to the consumer (e.g. bakeries, butchers)	Provide goods to consumer	Article
Importer	Importers of chemicals, intermediates, packaging, kitchen- and table ware, machineries, packaged food	Release goods from Third Countries in EU	Substance Intermediate Article
Consumer		Use FCM	Article

6.2 Table 2 – Business operators and their obligations in relation to DoC, supporting documents and labelling

Role	Goods	Receive Info	Keep Supporting documents	Next actor	Issue DoC	Labelling Art. 15
Non-plastic Manufacturer	Substance Intermediate	No	Yes	Manufacturer	Adequate Information	No
		Adequate information	Yes	Distributor	Adequate Information ⁶²	No
Plastic Manufacturer	Substance Intermediate	No	Yes	Manufacturer	Yes	No
		DoC	Yes	Distributor	Yes	No
Manufacturer	Article	DoC and Adequate Information	Yes	User	Yes	Yes
				Distributor	Yes	Yes
				Retailer + distribution centres	No	Yes
				Consumer	No	Yes
Distributor	Substance Intermediate	DoC	Yes	Manufacturer	Yes	No
		DoC	Yes	Distributor	Yes	No
Distributor	Article	DoC	Yes	User	Yes	Yes
		Labelling	Yes	Retailer + distribution centres	No	Yes

⁶² The non-plastic manufacturer has no legal obligation to issue Adequate Information, but is recommended to do so.

Role	Goods	Receive Info	Keep Supporting documents	Next actor	Issue DoC	Labelling Art. 15
Importer	Substance	Information	Yes	Manufacturer	Yes	Yes
	Intermediate	Information	Yes	Distributor	Yes	Yes
Importer	Article	Information + Labelling	Yes	User	Yes	Yes
				Distributor	Yes	Yes
				Retailer + distribution centres	No	Yes
				Consumer	No	Yes
User	Article	DoC + labelling	Yes	na ⁶³	na ⁶³	na ⁶³
Retailer and their distribution centre	Article	Labelling	Yes	Retailer	No	Yes
				Consumer	No	Yes
Consumer		Labelling				

⁶³ Materials and articles in contact with food, such as packaging, are not within the scope of this document

7 Abbreviations

<i>Abbreviation</i>	<i>Abbreviated term</i>
CAS	Chemical Abstracts Service
CLP	Classification, labelling and packaging of chemicals and mixtures
DoC	Declaration of Compliance
EC	European Community
EEA	European Economic Area
E-number	Code for food additives used in Europe
EPS	Expandable polystyrene
EU	European Union
EVOH	Ethylene Vinyl Alcohol copolymers
FCM	Food Contact Material
FL-number	Flavouring number
GMP	Good Manufacturing Practice
HDPE	High Density Polyethylene
LDPE	Low Density Polyethylene
LLDPE	Linear Low Density Polyethylene
MMML	Multi-Material Multilayer
OJ	Official Journal of the European Union
OML	Overall Migration Limit
PA	Polyamide
PAA	Primary Aromatic Amine
PET	Polyethylenetherephthalate
PP	Polypropylene
PS	Polystyrene
PVC	Polyvinylchloride
QM	Residual content
SML	Specific Migration Limit
SML(T)	Total Specific Migration Limit

8 Referenced legislation hyperlinks

Referenced legislation	Abbreviated Title	Hyperlink
Regulation (EC) No 1935/2004	Framework Regulation	http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2004R1935:20090807:EN:PDF
Regulation (EU) No 10/2011	Plastics Regulation	http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2011R0010:20111230:EN:PDF
Regulation (EC) No 2023/2006	GMP Regulation	http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:384:0075:0078:EN:PDF
Regulation (EC) No 1333/2008	Food Additives Regulation	http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:354:0016:0033:EN:PDF
Regulation (EC) No 1334/2008	Flavourings Regulation	http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:354:0034:0050:EN:PDF
Regulation (EC) No 1272/2008	CLP Regulation	http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:353:0001:1355:en:PDF
Recommendation 2011/696/EU	Nanomaterial Recommendation	http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:275:0038:0040:EN:PDF
Regulation (EC) No 882/2004	Control Regulation	http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2004R0882:20120101:EN:PDF