Explanatory Note

The Declaration of Compliance (DoC) applies to materials and articles intended to come into contact with foodstuffs as defined in the scope of Regulation 1935/2004/EC and Decree No. 2007-766 of 10 May 2007, as amended.
This declaration also applies to materials in contact with feed for farm animals and pets, as well as teats and pacifiers, still included in the scope of Decree 92/631.
In the case of a final article (packaging), it only applies to the empty article (before use, filling and sealing by the end user).

Important:
A DoC may cover a number of variations of a material or article that differ in size, shape, thickness, colour, or in the supply source of one or more components, resulting in a limited number of variations in the substances to be declared, provided that all substances to be declared are listed.
Where applicable, the compliance assessment must cover all variations. The document must identify the articles within a product family that it covers and also indicate the product on which the DoC is based. Documentation must be available to explain the reasons for the choice.
Differences in the substances to be declared due to variations in supply sources must be indicated, for example by means of an asterisk for the substances concerned.
Further information on the substances to be declared in the material or article must be made available to the customer and the competent authorities on request. The information provided must not be incorrect or inconclusive. A similar approach is recommended for adequate information.

No	Title of the question	How to respond	Explanatory remarks	Main points to watch out for user
1	**Identity of the business operator making the declaration**			**Check the role of the signatory – it must be relevant to the purpose of the document (e.g. not a marketer).**
	Ms/Mr	Delete as appropriate	This information is mandatory	
	Position	Indicate your position in the company	The signatory must be clearly authorised by their company to complete the declaration	
	Name and address of the company	Please note the name and address of the company making the declaration		
2	**Identity of the business operator who manufactures or imports the material and/or article covered by the declaration**			
	Name and address of the company	To be completed only if the manufacturer or importer is different from the operator making the declaration		
3	**Identity of the material and/or article covered by the declaration**			
	Description	The material and/or article must be clearly described and identifiable, accompanied by a photograph if possible.	The designation must be traceable, including in internal documentation such as analysis reports.	
	Reference	Indicate the supplier's reference number as communicated to the customer.	This may be the brand name, commercial reference, etc.	The technical data sheets are not linked to a single reference.
	Repeat component sentence	If the packaging is made of several materials, specify the different materials used. In the case of single-material items, specify the nature of the material. For packaging composed of inseparable elements, only one table should be completed. For packaging composed of separable elements, this table may be duplicated. In the column corresponding to the component, indicate the types of materials (not the commercial references).		

	In the case of multi-layer materials, specify the components from the inside to the outside - Specify whether any of the layers are functional barriers.	Indicate the layers covered by the declaration.	A declaration of compliance must always cover all materials and articles intended to come into contact with foodstuffs as delivered. A DoC covers a single packaging item. If several items enter in the composition of a packaging, a DoC per packaging item has to be provided, ex: a cereal box composed of a cardboard box and of a flexible plastic bag = 2 DoC.	
	Functional barrier in the case of multi-layer materials - Multi-layer plastics (Article 13(2), (3) and (4)) - Multilayer multi-materials (Article 14 § 2 and 3)	Tick the box if not applicable. Tick the corresponding box if the materials meet the requirements for the use of a functional barrier: only tick the box(es) after checking that no CMR substance (see sections 3.5, 3.6 and 3.7 of Annex I to the CLP Regulation) or nano substances (Commission Recommendation of 18 October 2011) are present.	Regulation (EU) 10/2011 defines multi-material multi-layer' as a material or article composed of two or more layers of different types of materials, at least one of them a plastic layer and 'plastic multi-layer' as a material or article composed of two or more layers of plastic.	Key point: check that the box is ticked to confirm that a functional barrier is provided with this material.
	- Specify whether the material covered by this declaration is to be used only behind a functional barrier	Tick the box if this is the case (material not suitable for direct contact).		
4	**Information on the end use of the material and/or article**	Here, you must specify the conditions under which the material or article is suitable for food contact.	Identify in particular any restrictions or limitations applicable to the conditions of use, in particular those resulting from restrictions and/or specifications concerning the substances used.	
	- Materials or articles intended for use in infant and young children food	Tick if applicable (Yes/No). If applicable, indicate the overall migration in mg/kg of food in relation to the actual surface area/volume ratio (note: the limit in Regulation 10/2011 applicable to plastics is < 60 mg/kg).	The conditions for verifying suitability for food contact may differ (e.g. plastic)	
	- Type of food intended to come into contact	Tick all types of foodstuffs for which food compliance is guaranteed. If a category of foodstuffs is not explicitly mentioned in the list, it can be specified in the "Other" category (e.g. fruit and vegetables to be washed, peeled or shelled fruits and vegetables, liquid foodstuffs - reference to water activity (Aw) possible) option to indicate the category number for plastics listed in Annex III of Regulation 10/2011). Where the reduction factors provided for in point 4.1 of Annex V to Regulation 10/2011 apply.	The types of contact are described in Regulation (EU) No 10/2011, as amended, Annex III. For foodstuffs not identified in the plastic regulations: - fruit and vegetables (fresh and whole) are treated as dry foodstuffs; - ice cream and frozen/deep-frozen foodstuffs are subject to separate categories to be ticked. Please note that it is also possible to carry out SML verification tests directly on foodstuffs (these tests take precedence over the previous ones). Be careful with materials or articles intended for infants and young children (to be specified).	Key point: check that the foodstuff actually packaged in the packaging for which the DoC is required corresponds to one of the categories ticked. Article 2.6 (1st paragraph) of Regulation 1935/2004: documentation shall be made available to the authorities upon request. The transmission of analysis reports is part of this documentation, which is not communicated.
	- Specify the standard conditions (test duration and temperatures) corresponding to the input data	Clearly specify the maximum processing and storage times and temperatures for which food safety is guaranteed (during processing and use by the consumer). Indicate, for example, for which use the packaging is suitable: traditional oven cooking, microwave cooking or filtration and, if critical, the time and temperature parameters. Support, link to the Ania fact sheet to help define customers' needs in terms of food contact packaging: https://www.ania.net/alimentation-sante/fiche-daide-a-lexpression-du-besoin-client-en-termes-demballage-pour-contact-alimentairecpla-france-championne-du-monde-de-lalimentation-copy	For plastics, this corresponds to the analysis conditions set out in Annex V of Regulation (EU) No 10/2011.	Key point: check that the foodstuff for which the material or article covered by this DoC is intended will be processed/transformed/stored under the conditions listed here. (e.g. packaging for a ready-made meal that must be reheated in a microwave, etc.)

	- Maximum ratio of surface area in contact with the foodstuff/volume used to establish the compliance of the material or article (if applicable).	Specify the ratio of the surface area in contact with the foodstuff to the highest volume for which compliance has been verified (in accordance with Articles 17 and 18 of Regulation 10/2011 or equivalent information). Specific requirements are applied to carboard material in the French legislation (Fiche MCDA N°4 V2 01.01.2019): specific migration values are expressed in mg/kg, based on the surface area/volume ratio under actual or foreseeable conditions of use (generally between 1 kg/10 dm^2 and 1 kg/50 dm^2 for cardboard food packaging) or, failing that, based on the maximum surface area/volume ratio mentioned in the declaration of compliance.	Required ratio for plastics (food contact suitability depends on this). For other materials, the ratio may be necessary to ensure compliance with restrictions.	Key point: the actual ratio must be lower than the maximum ratio indicated, and if this is not the case, the conditioner must carry out additional analyses to check whether compliance is OK for its specific application. This ratio must also be the most stringent used when verifying SML (see point 6).
5	**New regulatory references**	For packaging consisting of inseparable components, only one table needs to be completed. For packaging consisting of separable components, this table may be duplicated.	In the event of a change in the characteristics of the packaged product, its composition or its intended use, or in the event of a change in the conditions of use of the material or article, the recipient of this declaration must ensure the compatibility of the container and its contents, for which they alone are responsible.	Key point: - If the intended use of a package is changed, review at least all of the key notes below to verify that the DoC still applies. - Declarations relating to restrictions set out in other regulations (e.g. Agec law) must be made in a separate document.
	Cite the relevant texts	Indicate the reference of the relevant texts for the materials concerned: European and national legislation, Council of Europe resolutions, BfR recommendations, sectoral guides, etc. Thus, for materials that are not subject to national or European regulations, it is recommended to cite professional texts or official opinions where they exist.	The reference to the relevant texts is understood as the reference to the texts in force on the date of signature of this declaration. It is therefore not necessary to specify the amendments in force at the time of signing the declaration. Relevant changes in legislation and/or any changes in the substances or composition of the materials or in the purity affecting the DoC issued in accordance with this chapter require an update of the DoC. The customer must be informed by the supplier of these updates. In the case of a DoC covering several national legislations, these legislations shall be specified.	Key point for Regulation (EU) 2024/3190: For materials or articles falling within the scope of this regulation, list the bisphenols or bisphenol derivatives used in the manufacture of the material or article intended to come into contact with food.
	Special features (if applicable)			
	- Regulation (EC) No 450/2009	If applicable, specify the substance used and the number mentioned in the list of authorised substances for active or intelligent materials.	Please note that this point will only apply once the list of authorised substances in question has been published.	Pending the publication of authorisations, it may be useful to indicate the reference of the EFSA opinion on the process used and to check that any conditions of use are complied with.
	- Regulation (EC) No 2022/1616	If applicable, specify the type of material and the authorisation number of the recycling process mentioned in the EC process register.	Warning: - At the time of writing, some elements required for this DoC have not been published by the European Commission. The DoC remains mandatory according to the 2022/1616 model, even if some boxes cannot be filled in (RAN, NTN, etc.). - In the case of recycled plastics covered by Regulation 2022/1616, this declaration of compliance will therefore not be required. In the case of recycled plastics: use the declaration of compliance template in accordance with Regulation 2022/1616.	
6	**Information relating to the material and/or article covered by the declaration**	Tick the appropriate box(es).		
	- Supplier declarations	Tick the box if applicable	NA for glass	
6.1	**Overall migration analyses**	Specify the simulants and test conditions if relevant (a blank table and an unchecked box = not relevant). It is not mandatory to communicate the analysis results themselves, or even the name of the laboratory (documentation available on site). The tests are carried out according to the target population (see point 8).	This point does not currently apply to glass, multi-material and multi-layer materials and articles*. *Changes planned by Regulation 2025/351 amending Regulation 10/2011. Certain types of cardboard and paper may be affected (2019 update to the DGCCRF (French authority) fact sheet).	Pending the entry into force of Regulation 2025/351, the DGCCRF (French authority) recommends: "In the case of multi-layer multi-material materials and articles, where the layer in direct contact with food is made of plastic, verification of compliance with Article 3 of the Plastics Framework Regulation (specific and overall migration) shall be carried out on the finished product on the basis of the rules and limits laid down in Regulation (EU) No 10/2011".

6.2	**Information on restricted substances**	If a restricted substance also has a DUA code, it must be listed in the table of dual-use additives in addition to the table of restricted substances.	SMLT = Cumulative limits for several substances. MQ = Maximum quantity (of a material, note that this is not a specific limitation) SML = Specific migration limit Clarification of the concept of worst case: Worst case = simulation in which it is assumed that all of the substance migrates. The worst case can be calculated or analysed, and the data can also be provided by the supplier. For plastics, compliance with the limits is required by Article 16 of Regulation (EU) No 10/2011. For other materials, refer to the reference texts.	
	Specify below the substance(s) subject to restriction and the permissible limit(s).	Substances must be identified by their names and a reference number (CEE or CAS) and the permissible limits must be specified.	Restrictions are understood to mean: content criteria (MQ), purity criteria (e.g. paper/cardboard), specific migration limits, specific release limits, etc.	
	If not completed, specify the reasons	- Where there are no restricted substances (plastic): specify this ("absence of ..."). - Where substances cannot be released above the specified limit: specify this explicitly - Where the criteria are common to an entire sector: refer to the relevant sectoral reference document.	Purity criteria: paper and cardboard, for example, refer specifically to the purity criteria listed in the DGCCRF (French authority) sheet. Please note that if the packaging is a multi-material, multi-layer packaging containing a plastic layer, the SMLs do not apply*. With the exception of restrictions relating to vinyl chloride monomer. *Changes planned by Regulation 2025/351 amending Regulation 10/2011.	Pending the entry into force of Regulation 2025/351, the DGCCRF (French authority) recommends: "In the case of multi-layer multi-material materials and articles, where the layer in direct contact with food is made of plastic, verification of compliance with Article 3 of the Plastics Framework Regulation (specific and overall migration) shall be carried out on the finished product on the basis of the rules and limits laid down in Regulation (EU) No 10/2011".
	Specify how compliance with these limits has been established	- If specified by analysis, specify the simulant(s) used and the test conditions. - If by other means (calculation, modelling), specify which ones.	Please note that these analyses, even for regulated substances, may be based on supplier data, depending on the operator's position in the value chain and any prior worst-case calculations/modelling (to be specified). It is not mandatory to communicate the analysis results themselves, or even the name of the laboratory.	Be careful with the ratio(s) used in the different verification methods: these must be consistent with the maximum ratio indicated in point 8. Key point : the use of the S/V ratio in relation to closures.
6.3	**Information on dual-use additives**	Definition of dual-use substance: a dual-use substance is used as a material in the formulation of the packaging and may also be found in the composition of a foodstuff, so the concentrations may add up, and it is therefore important to inform customers. Refer to Regulations 1333/2008 and 1334/2008. If a restricted substance also has a DUA code, it must be listed in the table of dual-use additives in addition to the table of restricted substances.	Definition of dual-use substance: a dual-use substance is used as a material in the formulation of the packaging and may also be found in the composition of a foodstuff, so the concentrations may add up. It is therefore important to inform customers.	
	Use of dual-function additives, as indicated by the user (food additive E... or flavouring substance FL...)	Tick the box if not applicable (+ no use of dual-use additives) Specify the substance(s) concerned by completing each column of the table: Name, Identification (E number or FL number listed in the relevant regulations), with the optional option of the content used.	Refer to Regulations 1333/2008 and 1334/2008.	The food manufacturer must ensure compliance with the restrictions laid down in Regulations 1333/2008 and 1334/2008 according to the additives declared.

6.4	**Assessment of intentionally added non-listed substances**	In accordance with Article 8.2 of Regulation 1935/2004, no substance shall be authorised unless it has been adequately and sufficiently demonstrated that, when used in accordance with the conditions to be laid down in the specific measures, the final material or article complies with the requirements set out in Article 3 and, where applicable, Article 4. In the absence of a risk assessment, list the substances that may pose a risk in the table, specifying their names and identification numbers (reference number of your choice).	Reference text: refer to the reference text for the material(s) used in the manufacture of the packaging. E.g. Swiss ordinance for inks; BfR XXXVI for paper and cardboard; etc.	Ultimately, the person placing the final article on the market must ensure that the risk assessment has been carried out on all materials used to declare the conformity of the final packaging.
6.5	**Assessment of unintentionally added substances**	In accordance with Article 8.2 of Regulation 1935/2004, no substance shall be authorised unless it has been adequately and sufficiently demonstrated that, when used in accordance with the conditions to be laid down in the specific measures, the material or article complies with the requirements referred to in Article 3 and, where applicable, Article 4, including adequate information on the presence of unintentionally added substances, if present in a quantity that could cause a final material to not comply with Article 3 of Regulation (EC) No 1935/2004. In the absence of a risk assessment, list the substances that may pose a risk in the table, specifying their names and identification numbers (reference number of your choice). In the comments column, you can specify the test conditions, the method used, the quantities detected, etc.		Ultimately, the person placing the final article on the market must ensure that the risk assessment has been carried out on all materials used to declare the conformity of the final packaging.
6.6	**Sensory test(s)**	At a minimum, details regarding the type of matrix (acidic/neutral product) and the conditions under which the sensory test was carried out. Standards are available, for example: ISO 13302, DIN 10955, EN 1230 (specific to paper/cardboard).	As a reminder, Article 3 of Regulation 1935/2004 states: 1. Materials and articles, including active and intelligent materials and articles, shall be manufactured in accordance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer constituents to food in quantities that could: (a) present a hazard to human health, or (b) cause an unacceptable change in the composition of the foodstuffs, or **(c) cause an unacceptable change in the organoleptic characteristics of the food.**	
7	**Done at,**	Indicate the date of signature of the DoC. Indicate the location.	The validity of a DoC depends on changes made to the article or its use,-on regulatory changes, changes in the conditions under which migration tests are carried out, changes in the applicable regulations, or if the conditions for migration analysis are modified. The publication of an amendment does not require the DoC to be updated if it does not affect the subject of the declaration.	Key point: the DGGCRF (French authority) recommends a maximum validity period of five years for test report. If changes likely to affect the inertia of the material have occurred during this period, the tests must be repeated.
	Signature and stamp of the company	The signatory must be authorised to do so.		