Instructions for completing the Declaration of Compliance with food contact legislation

The Declaration of Compliance concerns materials and items intended to come into contact with food as defined in the scope of Regulation 1935/2004/EC and the amended Decree No. 2007-766 from 10 May 2007.

This report also applies to materials in contact with livestock and domestic animal foods, as well as teats and pacifiers, still included in the scope of Decree 92/631.

Regarding a final article (packaging), it concerns only the empty item (before use, filling and closing).

Important:

A Declaration of Compliance (DoC) may cover a number of variations of a material or item that differ in size, shape, thickness, or color in the source of supply of one or a few components, resulting in a limited number of variations in the substances to be declared, provided that all the substances to be declared are listed.

Where applicable, the compliance assessment should cover all variations. The document must identify the objects of a family of products covered and also indicate the product on which the DoC is based. Documentation must be available to give reasons for the choice. Differences in reportable substances due to variations in sources of supply should be reported by using, for example, an asterisk for the relevant substances.

Further information on the reportable substances of material or item must be made available upon request to the client and the competent authorities. The information provided must not be erroneous or inconclusive. A similar approach is recommended for the appropriate information.

N°	Title of the question	How to answer it	Explanatory remarks	Main points of vigilance for the User
1	**Identity of the operator making the declaration**			**verify the signatory's position - it must be relevant for the establishment of this document (e.g. not a marketer or commercial person)**
	Mr/Mrs	Cross out where necessary	This information is mandatory The signatory must be clearly mandated by his/her company to fill-in this report	
	Position	Write down your position in the company		
	Company Name and Address	Write down the name and address of the company filing the report		
2	**Identity and address of the business operator who manufactures or imports the materials and/or items covered by this**			
	Company Name and Address	To be completed only if the manufacturer or importer is different from the operator making the report		

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3	**Identity of the material and / or item covered by this declaration**			
	Description	The material and / or the article must be clearly described and identifiable, if necessary add a picture	The designation must be traceable, also in internal documentation such as analysis reports.	
	Trade name and Reference	Indicate the supplier reference number as communicated to the client	It can be the brand name, sales reference …	Data sheets are not linked to a single reference.
	Indicate the component material(s) of the item	If a packaging is composed of several materials, specify the different materials used. In the case of mono materials, specify the nature of the material		
	In the case of multi-layer materials, specify the components - from the inner to the outer layer - specify whether one of the layers is a functional barrier	Display the layers included in the report	A DoC must always cover all materials and items intended to come into contact with food as delivered, and it must be described	
	Statement issued on	Indicate the DoC signature date	The validity of a DoC depends on the changes made to the article or on the use of the latter, or regulatory changes or conditions for carrying out migration tests or regulation or if changing the migration analyses conditions. The publication of an amendment does not result in an update of the DoC where this has no impact on the purpose of the report.	Point of vigilance: the DGGCRF (Directorate General for Competition, Consumer Affairs and Prevention of Fraud) suggests a maximum duration of 5 years for the validity period of the test reports; if changes that may cause a change in the inertness of the material have occurred during this period, the tests must be repeated.

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4	**Confirmation that those materials or items meet the relevant requirements of Food contact regulations**		In the event of a change in the characteristics of the packaged product, its composition or its destination, and in the event of a change in the conditions for the use of the material or the item, the person to whom this declaration is addressed shall ensure the container / content compatibility for which s/he bears sole responsibility.	Vigilance point for the user: in the event of packaging's destination modification, review, at least, each point of vigilance listed below to check that the DoC still applies
	Quote the relevant texts	Indicate the reference of the relevant texts for the relevant materials: European and national legislation, Council of Europe resolutions, BfR advice, sector guides etc. Thus, for materials that do not have national or European regulations, it is recommended that professional texts or notices of official instance are cited - where these exist.	The reference to the relevant texts is understood as the reference to the texts in force on the day this Doc has been signed. It is therefore not necessary to specify the amendments in force when the DoC has been signed. Relevant changes in the legislation and / or any changes in the substances or in the composition of the materials or in the purity affecting the DoC issued in accordance with this Chapter shall require an update of the DoC. The supplier must notify these updates to the client. In the case of a DoC taking into account several national laws, these laws are specified.	
	Particularities (if applicable)			
	- (EC) Regulation N° 450/2009	If relevant, specify the substance used and the number appearing in the Community list of substances that may be used in active or intelligent components	Note that this point will only be applicable as of the publication of the list in question	Pending the publication of the authorizations, it may be useful to indicate the reference of EFSA's opinion about the process used and to check that any conditions of use are met.

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	- (EC) Regulation N° 282/2008	If applicable, specify the type of material and the authorization number of the recycling process mentioned in the EC process register	Note that this point will only be applicable as of the publication of the register in question	
	This declaration of compliance has been established in respect of the following	Tick any appropriate boxes		
	-Declarations by suppliers of raw materials	Tick any appropriate boxes	N/A for glass	
	- Overall migration testing	Specify the simulants and test conditions if applicable (an empty table and an unchecked box = not applicable). Communication of analysis results or the laboratory name is not mandatory (documentation available on site). The tests are carried out according to the target population (see point 8)	This point does not apply to glass, cardboards an paper packagings, and multi-layer materials and articles. (update 2019 of the DGCCRF form).	
	- Assessment of non-listed substances (see Article 6 of Regulation 10/2011): risk assessment and / or list of substances	In the absence of a risk assessment, list the substances that are potentially at risk in the table by specifying the names and identification numbers (choice of reference number)	Applicable only to plastics (Article 6 of Regulation 10/2011): for other materials, tick the box "not applicable"	Ultimately, the end-product marketer (the operator placing the material or article on the market) must perform the risk assessment if it has not previously been done.
	- NIAS: risk assessment and / or list of substances (see Article 6 of Regulation 10/2011)	In the absence of a risk assessment, list the substances that are potentially at risk in the table by specifying the names and identification numbers (choice of reference number)	Only applicable to plastics: for other materials, tick the box "not applicable"	Ultimately, the end-product marketer must perform the risk assessment if it has not previously been done.

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5	**Information on substances with restrictions**			
	Specify below the substance(s) subject to restriction and migration limit(s)	Substances must be identified by their names and a reference number (EEC or CAS) and migration limits, specified	Restrictions include: the content criteria (CC), purity criteria (e.g. paper / cardboard), specific migration limits (SML), specific release limits ...	
	Specify how compliance with these limits has been established	- In the case of tests, specify the simulant(s) used, and tests conditions - If by other means (calculation, modeling), specify which ones	Note that these analyses, even for controlled substances, are not mandatory, depending on the position of the operator in the value chain and any calculations of the worst / pre-initialized modeling (to be specified). Communication of analysis results or the laboratory name is not mandatory.	Verify the ratio(s) used in the different verification methods used: these must be consistent with the max ratio indicated in point 8 **A point of vigilance on the use of the S/V ratio in the frame of the closing elements closures.**
	If not completed, specify the reasons	- Cases where there are no restricted substances (plastic): specify as ("absence of ...") - Cases where substances cannot be released beyond the specified limit: be clearly specific - Cases where the criteria are common to an entire sector: refer to the sectorial reference document	Purity criteria: paper/cardboard, for example, refers specifically to the purity criteria listed in the DGCCRF sheet. Note that if the packaging is a multi-material multi-layers containing a layer of plastic material, the SML do not apply. Excluding the vinyl chloride monomer restrictions.	DGCCRF Advice: "In the case of multi-layer materials and items, where the layer in direct contact with foodstuffs is made of plastic, the verification of a finished product's compliance with Article 3 of the Plastics Framework Regulation (specific and global migration) is carried out on the basis of the rules and limitations laid down in (EU) Regulation N° 10/2011 "

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	Information on dual-use additives Use of dual functional additives, as indicated by the user (food additive E ... or flavoring substance FL ...)	Tick the box if it is not applicable (+ no use of dual-use additives) Specify the relevant substance(s) by filling in each column of the table: Name, Identification (number E or FL entered in the corresponding regulations), with content used in option.	Some substances used in FCM are also food additives / flavorings authorized respectively by (EC) Regulation N° 1333/2008 or (EC) Regulation N° 1334/2008. These substances are called dual-use additives. For plastics, there is a non-exhaustive list in the EU Guideline on Regulation N° 10/2011 concerning plastic materials and items intended to come into contact with food with regard to information in the supply chain	The food manufacturer must ensure compliance with the restrictions laid down in Regulation 1333/2008 and 1334/2008 according to the additives declared
6	**Information related to the final use of materials or items**	Here, the conditions under which the material or item is suitable for food contact must be specified.	Identify in particular any restrictions or limitations applicable to the conditions of use, including those resulting from restrictions and / or specifications concerning the substances used	
	- Materials or items intended for infant and young children	Tick if applicable (Yes / No)	The conditions of verification of suitability for food contact may be different (case of plastic)	

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	- Type of foodstuff intended to be placed in contact	Tick all types of food for which food compliance is guaranteed. If a category of food is not mentioned explicitly in the list, it can be specified in the category "Other" (e.g. fruits and vegetables to be washed, peeled or nuts) you can indicate the number of the category for plastics indicated in Appendix III of Regulation 10/2011. Where the reduction factors provided for in point 4.1 of Appendix V of Regulation 10/2011 apply.	The types of contact are described in amended (EU) Regulation N° 10/2011, Appendix III. For commodities not identified in the plastic regulations: - fruits and vegetables (fresh and whole) are assimilated to dry foods; - ice-cream and frozen / deep frozen foods are subject to separate categories which are to be ticked. Note that it is also possible to perform SML verification tests directly on food (these tests prevail over previous ones). Be vigilant with materials or articles intended for infant and young children (to be specified)	Vigilance point for the user: check that the food actually packaged in the packaging for which the DoC is required is one of the categories ticked. Article 2.6 (1st paragraph) of Regulation1935/2004: documentation is made available to the authorities upon request. Transmission of analysis reports are part of this documentation which is not communicated
	- Specify the standard conditions (time and test temperatures) corresponding to the input data	Clearly specify the maximum processing and storage times and temperatures for which food compliance is guaranteed (during the process and when use by the consumer). Indicate, for example, how the packaging is used: traditional oven cooking, microwave cooking or filtration and if critical, time and temperature settings	For plastics, this corresponds to the analysis conditions provided for in Appendix V to (EU) Regulation N° 10/2011.	Vigilance point for the user: check that the foodstuff for which the material or the item covered by this DoC is going to be processed / transformed / stored under the conditions listed here. (for example, packaging for a cooked dish that must be heated in the microwave etc.) This ratio must also be the most severe used when verifying the SML (see point 6).

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	- Maximum surface / volume ratio in contact with food used to established compliance of the material or item (if applicable)	Specify the ratio of the contact surface with food / highest volume whose conformity has been verified (in accordance with Articles 17 and 18 of Regulation 10/2011 or equivalent information).	Ratio required for plastics (suitability for food contact depends on this). For other materials, the ratio may be necessary to ensure compliance with the restrictions.	Point of vigilance for the user: the actual ratio must be less than the indicated max ratio, and if not, the packer must perform additional analyses to verify if compliance is OK for its specific application.
7	**Functional barrier in the case of multilayer materials** - Multilayer plastics (Article 13 (2), (3) and (4)) - multi-layer materials (Article 14 (2) and (3))	Tick the box if not applicable		
		Tick the corresponding box if the materials meet the requirements provided for use of a functional barrier: check the box(es) only after having checked that no CMR substance (see sections 3.5, 3.6 and 3.7 of the Appendix I to the CLP Regulation) or nano (Commission Recommendation from October 18th 2011) is present.		
	- Specify whether the material covered by this declaration is to be used only behind a functional barrier	Tick the box if it is the case (material not suitable for direct contact)		Point of vigilance for the user: if the box is ticked, check that a functional barrier is provided with this material
	Signed in:	Write in city name		
	Signature	The signatory must be authorized to do so		