



WG DoC

28/1/2021

DECLARATION OF CONFORMITY

First real proposition by the commission

- New harmonised template fits in revision of the FCM-legislation → Obligation for all FCM to deliver a DoC.
- In the Future → digitalisation

This exercise has 2 goals:

- Is the Fetra DoC fit for use?
- Remarks on the EU -Comm proposal?

We can bring this to the FS public health in a bilateral dialogue.

Structure: 5 sections

- Pre-amble, general and specific rules
- Sections:
 1. Identification
 2. Compliance information
 3. Information for the users of the product (including end-users)
 4. Signature
 5. Annexes
- Maximum field lengths
 - to ensure DoC stays relevant, concise and clear
 - to facilitate digital DoC

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Pre-Amble

- Rules on the use of the DoC
 - number of characters
 - possibly further administrative rules needed;
- registration number – to contact competent authority
- use of sections 2.3 and 2.4 – how to use, which substances
- Non-Disclosure Agreements
- Signing
- Digital documents

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Section 1

DECLARATION of COMPLIANCE with REGULATION (EU) 10/2011

I, the undersigned in section 4 declare in name of [ADD NAME OF Manufacturer] as identified in section 1.1, that the plastic material identified in section 1.2 was produced in accordance with Regulation (EU) No 10/2011. The product to which this declaration applies is suitable for use in contact with food, provided it is used in accordance with the restrictions set out section 3 of this declaration, to which purpose I provided adequate instructions in this declaration, and labelling on the product.

Hereby I declare the contents of this declaration is correct to the best of my knowledge and in compliance with Regulation (EU) No 10/2011.

Section 1 Identification

1.1 Manufacturer		1.2 Plastic product		1.3 competent authority	
1.1.1 name	50	1.2.1 tradename / designation	50	1.3.1 name	50
1.1.2 address	100	1.2.2 Production stage	<input type="checkbox"/> Intermediate <input type="checkbox"/> final* (check one)	1.3.2 address	100
1.1.3 country	50	1.2.3 other info identifying the product (add image or other additional information to annex in section 5)	100	1.3.3 country or region	50
				1.3.4 reg. number	50
[note – section 2 of Annex IV is omitted – is there really a need for this – can this be done differently?]					

(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;

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CORRESPONDING PART IN THE FETRA-DoC

Identification

Declaration of Conformity	
Nr	
Date	
Supplier	
Address	
Phone Nr	
E-mail	
Contact Person	

Section 2

Section 2: Compliance information		
2.1 general		
2.1.1	<input type="checkbox"/> yes	the plastic materials or articles, products from intermediate stages of manufacture or the substances meet the relevant requirements laid down in this Regulation and in Article 3, 11(5), 15 and 17 of Regulation (EC) No 1935/2004;
2.1.2	<input type="checkbox"/> yes <input type="checkbox"/> N/A	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.
2.2 Specifications on the use of the material or article:		
2.2.1	type or types of food with which it is intended to be put in contact	100
2.2.2	time and temperature of treatment and storage in contact with the food;	100
2.2.3	the highest food contact surface area to volume ratio for which compliance has been verified in accordance with Article 17 and 18 or equivalent information	100
2.2.4	Limitations on use in final products	100
2.2.5	Other relevant specifications	100

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Specifications of use

Packaging suitable for		
Food contact		
Dry food (powder)		
Fatty food		
Moist and aqueous food		
Liquid food		
Acidic food		
Frozen food		
Packaging material designed to be heated together with food products (max.temperature, time)		
Presence of a plastic layer (coating/other)	No	
	Yes	
	Material	
Necessity of a functional barrier		
Yes		
No		
Food products have to be		
• Peeled		
• Washed		
• Cooked		

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Applicable legislation

We declare that the above mentioned products meet the requirements of the following:	
• (EU) 1935/2004	regulation on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC
• (EU) 2023/2006	regulation on good manufacturing practice for materials and articles intended to come into contact with food
• The inks used meet the requirements of EuPIA guidance	
• (EU) 10/2011	regulation on plastic materials and articles intended to come into contact with food
• Royal Decree of 11 May 1992	on materials and articles intended to come into contact with food

Section 2.3/2.4

2.3 Substances (presence) – only list substances subject to specific restrictions, including NIAS if so									
Number	FCM No (if any)	CAS Nr (if any)	Name / other identification / NDA code	amount	Unit 1: mg/kg f 2: mg/dm ² 3: mg/kg p 4: % w/w	Basis art. 5 or art. 6 **	Dual use	Nano	Table 1 Annex II/ genotoxic
1			50				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2							<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3							<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4							<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
...			Add additional substances as appropriate				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.4 Substances (compliance) – substance numbers shall be the same as in section 2.3									
Number	Aplicable SML	Aplicable SML (T)	Compliant with applicable SMLs	NDA information available	S/V test	Applicable or internal purity specifications	compliant	Other restrictions in table 1 of Annex I	Compliant
1			<input type="checkbox"/> yes <input type="checkbox"/> N/A	<input type="checkbox"/> yes <input type="checkbox"/> N/A		100	<input type="checkbox"/> yes <input type="checkbox"/> N/A	100	<input type="checkbox"/> yes <input type="checkbox"/> N/A
2			<input type="checkbox"/> yes <input type="checkbox"/> N/A	<input type="checkbox"/> yes <input type="checkbox"/> N/A			<input type="checkbox"/> yes <input type="checkbox"/> N/A		<input type="checkbox"/> yes <input type="checkbox"/> N/A
3			<input type="checkbox"/> yes <input type="checkbox"/> N/A	<input type="checkbox"/> yes <input type="checkbox"/> N/A			<input type="checkbox"/> yes <input type="checkbox"/> N/A		<input type="checkbox"/> yes <input type="checkbox"/> N/A
4			<input type="checkbox"/> yes <input type="checkbox"/> N/A	<input type="checkbox"/> yes <input type="checkbox"/> N/A			<input type="checkbox"/> yes <input type="checkbox"/> N/A		<input type="checkbox"/> yes <input type="checkbox"/> N/A
...			<input type="checkbox"/> yes <input type="checkbox"/> N/A	<input type="checkbox"/> yes <input type="checkbox"/> N/A			<input type="checkbox"/> yes <input type="checkbox"/> N/A		<input type="checkbox"/> yes <input type="checkbox"/> N/A

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Tests – to be elaborated

- Worst case calculation
- Migration testing
- Other ???

Following tests were carried out – According to regulation EU 10/2011 with amendments			
Laboratory			
Address			
Date			
Overall migration (if applicable)	result	mg/dm ²	
Simulant	Protocol	Result	
List of monomers with a restriction			
Monomer	Ref. Nr or CAS Nr	Restriction (ex SML)	

Section 2.5

2. 5 adequate information not specified in section 2.2, 2.3 or 2.4		
2.5.1	Other 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;	1000
2.5.2	Other adequate information relative to the substances which are subject to a restriction in food, marked as 'Dual Use' in section 2.3, 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;	1000
2.5.3	Any other information relevant for achieving compliance	1000
2.5.4	Instructions for receiving information under NDA, including address of third party that holds this data, if any – note this information shall always be provided to competent authorities on their request without delay	1000

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Section 3

Section 3: instructions and information to users of the product		
3.1	Instructions to converters – leave fields empty or indicate N/A if none	
3.1.1	Maximum use (%)	% (% recycled material in final/intermediate material, if any maximum)
3.1.2	Restrictions of use**	500
3.1.3	Other instructions	500
3.2	Instructions to users further down the supply chain, including end users – leave fields empty or indicate N/A if none	
3.2.1	Restrictions of use**	500
3.2.2	Summary of labelling	500
3.2.3	Other instructions	500

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Specifications of use: more information?

Primary packaging designed to package food products			
Article Nr			
Article description			
Manufacturer (if different from the supplier)			
Materials			
Material	Substrate		
	Layer		
	Layer		
Composite material	Percentage	%	
	Percentage	%	
	Percentage	%	
Dimensions	(L x w x h), diameter	mm	
	Thickness	mm	
Weight		g	
Colours	Number	#	
	Colours		
	Printing technique		

Section 4 and 5

Section 4: Signature	
4.1 Signature (Add Signature, place, company stamp)	
4.2 Name of person signing	50
4.3 Date of the declaration	
5 Annexes – in case the maximum field length is too short add additional information, please add that to the annex fields below – add a line for every field.	
Field	Information
x.y.z	(unlimited field length, however, per field not more than two pages should be used, images/graphs/tables may be added as required)

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Signature

Date	Name	Function	Signature