

Example of a DoC for Plastic FCMs

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DECLARATION OF COMPLIANCE		
Manufacturer	Hegarty S.A. Av. De las Violetas, s/n Poligono Industrial Monfort, Sevilla, SPAIN	
Product covered by this declaration	PET Box SN.4563	
Date of the declaration	25.09.2014	
Declaration of compliance with		
<ul style="list-style-type: none"> This product complies with Regulation (EC) No. 10/2011 (as amended). This product complies with Regulation (EC) No. 1935/2004 (as amended). This product complies with Regulation (EC) No. 2023/2006 (as amended). 		
<p>This plastic box has been manufactured only with monomers, other starting substances and additives that are authorised under Regulation (EC) No. 10/2011. A risk assessment according to Article 19 of Regulation (EC) No. 10/2011 was performed for this product.</p>		
Information about the compliance of substances used that are subject to any restriction or specification		
Compliance with overall migration limit	Overall migration is below 10mg/dm ² under standard testing conditions laid down in Regulation (EC) No. 10/2011. Additional information can be provided on request.	
Individual substances	Specific Migration Limits (SMLs)	Test results (or estimated level of migration from calculations)
1. 1-hexene	3 mg/kg	SMLs cannot be exceeded for s/v contact ratio below 6 dm ² /kg.
2. Isophthalic acid	5 mg/kg	
Information about the compliance of substances subject to purity criteria.		
There are no substances subject to purity criteria. There are no substances subject to restrictions apart from the Specific Migration Limits (SMLs).		
Information about the use of "dual-use" additives in the material.		
No dual use additives were used in the manufacture of this product.		
Conditions of use		
<ul style="list-style-type: none"> Type(s) of food with which it is intended to be put in contact All foods. Time and temperature and storage while in contact with the food Cold storage for up to 10 days. The ratio of food contact surface area to volume used to establish the compliance of the material or article The compliance testing was done under conditions set out in Regulation (EC) No. 10/2011 using a surface to volume (s/v) contact ratio of 6 dm²/kg. 		
Functional Barrier		
There is no functional barrier present.		

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The identity and address of the business operator issuing the declaration of compliance

A DoC needs to contain information to ensure that the product is traceable if needed.

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The identity and address of the business operator that manufactures or imports the FCM

This information, together with that contained in point one above will help determine responsibility and traceability of the FCM if necessary.

Manufacturer	Hegarty S.A. Av. De las Violetas, s/n Poligono Industrial Monfort, Sevilla, SPAIN
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The identity of the product

Including the trade name, manufacturer's code, catalogue reference number or any other code identifier that will allow the downstream user to adequately identify and trace the material.

Product covered by this declaration	PET Box SN.4563
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The date of the declaration

This date indicates that the product was compliant with the legislation in place at that time.

Given that the legislation is ever evolving, it is possible that it can become more restrictive and compliant products can subsequently become non-compliant due to legislative amendments.

Date of the declaration	25.09.2014
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Confirmation that the FCM complies with all applicable regulations

Including confirmation that migration from the FCM does not exceed the Overall Migration Limit (OML) and does not alter the organoleptic properties of the food.

Declaration of compliance with	
<ul style="list-style-type: none"> This product complies with Regulation (EC) No. 10/2011 (as amended). This product complies with Regulation (EC) No. 1935/2004 (as amended). This product complies with Regulation (EC) No. 2023/2006 (as amended). 	
<p>This plastic box has been manufactured only with monomers, other starting substances and additives that are authorised under Regulation (EC) No. 10/2011. A risk assessment according to Article 19 of Regulation (EC) No. 10/2011 was performed for this product.</p>	
Information about the compliance of substances used that are subject to any restriction or specification	
Compliance with overall migration limit	Overall migration is below 10mg/dm ² under standard testing conditions laid down in Regulation (EC) No. 10/2011. Additional information can be provided on request.



Adequate information in relation to the substances used in the manufacture of the FCM.

Confirmation that Specific Migration Limits (SMLs) and any other restrictions established for them in Annex I of Regulation (EC) No. 10/2011 are being complied with.

Individual substances	Specific Migration Limits (SMLs)	Test results (or estimated level of migration from calculations)
1. 1-hexene	3 mg/kg	SMLs cannot be exceeded for s/v contact ratio below 6 dm ² /kg.
2. Isophthalic acid	5 mg/kg	



Dual-use additives

Dual-use additives are substances that can be used by food business to perform a technological function in food as well as having a function as additives in the manufacture of certain FCMs. Information on the use of dual-use additives should be provided to guarantee they are compliant with the legislation applying to Food Additives/Flavourings and Food Contact Materials.

Information about the compliance of substances subject to purity criteria.
There are no substances subject to purity criteria.
There are no substances subject to restrictions apart from the Specific Migration Limits (SMLs).
Information about the use of "dual-use" additives in the material.
No dual use additives were used in the manufacture of this product.



Specifications on the use of the FCM

This includes the type(s) of food, maximum contact time, surface to volume ratio (s/v) and temperature of use of the FCM in order to guarantee that the migration limits are complied with and the product is safe.

Conditions of use
<ul style="list-style-type: none"> • Type(s) of food with which it is intended to be put in contact All foods. • Time and temperature and storage while in contact with the food Cold storage for up to 10 days. • The ratio of food contact surface area to volume used to establish the compliance of the material or article The compliance testing was done under conditions set out in Regulation (EC) No. 10/2011 using a surface to volume (s/v) contact ratio of 6 dm²/kg.



Functional barrier

A 'functional barrier' is a layer within multi-layer food contact materials or articles that acts preventing (totally or partially) the migration of substances from other layers behind that barrier into the food. This point on the DoC includes confirmation that the functional barrier (if present), as well the material or article itself, complies with all applicable requirements. If there is no functional barrier, stating the absence of one is considered good practice.

Functional Barrier
There is no functional barrier present.