# DECLARATION OF COMPLIANCE WITH REGULATIONS ON MATERIALS AND ARTICLES INTENDED TO COME IN CONTACT WITH FOOD

*This declaration of compliance (DoC) template and the accompanying Explanatory notes, designed to assist in the completing the DoC template, have been developed by the PAE (French Food and Packaging Platform). Both documents are available on the ANIA website and are provided for information purposes only. This document aims at facilitating the relationship between suppliers and downstream business operators in the supply chain of materials, packaging and articles (excluding equipment) that come into contact or are likely to come into contact with foodstuffs. This template aims at informing them about how to comply with the obligations laid down in Articles 3 and 16 of Regulation (EC) No 1935/2004 and in other relevant measures (see details in part 5).*

*In compliance with the principles of competition law, each company remains free to adopt, modify or replace this template with a document of its own design, according to its needs and specific situation. The use of this template is strictly optional and is not imposed by the PAE or any other entity.*

*Each declarant is responsible for the declarations made. PAE declines all responsibility.*

# Identity of the operator making the declaration

Ms/Mr : ………………………………………………………………………………………………………………………….

Position: …………………………………………………………………………………………………………………………………………….

Company name and address: …………………………..………………………………………………………………………………

…………………………………………………………………………………………………………………………………………………………….

# Identity of the business operator who manufactures or imports the material and/or article covered by the declaration (if different)

Company name and address: …………………………..……………………………………………………………………….……...

……………………………………………………………………………………………………………………………………………………………

Specify:  Manufacturer  Importer

# Identity of the material and/or article covered by the declaration

Identify the material(s):

Description

……………………………………………………………………………………………………………………………………………………………

**Commercial reference(s) or customer**: …………………………………………………………………………………………………………………………………………………………….

**Indicate the components of the material(s) constituting the structure of the article:**

*In the case of multi-layer materials, specify the components from the inside (in contact with the food) to the outside (specify if one of the layers is a functional barrier)*:

|  |  |  |
| --- | --- | --- |
| Component no. | Type of material/Description | Any additional information for customers (optional) |
| 1 |  |  |
| 2 |  |  |
| 3 |  |  |
| 4 |  |  |
| … |  |  |

Packaging assembly (held together by adhesive, etc.): …………………………………………………………………………………………………………………………………………………………….

# Functional barrier (FB) in the case of multi-layer materials  Not applicable

Or tick the appropriate box if the materials meet the requirements for the use of a FB:

 Multilayer plastics (Article 13(2), (3) and (4) of Regulation (EU) No 10/2011)

 Multilayer multi-materials (Article 14(2) and (3) of Regulation (EU) No 10/2011)

 The material covered by this declaration must only be used behind a FB

 Other materials - specify: ……………………………………………………………………………………………………………

……………………………………………………………………………………………………………………………………………………………

# Information on the end use of the material or article

**Material or article intended for use in infant and young children food**  Yes  No

**Type of food intended to come into contact with the material and/or article:**

 All types of foodstuffs

or

 Dry foodstuffs and similar products

 Moist foodstuffs/aqueous products

 Acidic foodstuffs (pH ≤ 4.5)

 Alcoholic foodstuffs – Specify the alcohol content: ………………….

 Frozen and deep-frozen foodstuffs – Specify whether the foodstuffs are frozen/deep-frozen/defrozen in their packaging or outside their packaging: ……………………………………………………………………………..

 Fatty foodstuffs:

*If the material and/or article subject to Regulation (EU) No 10/2011 is affected by the application of a reduction factor, indicate:*

 Fat Reduction Factor

 Reduction factor related to simulant D2

 Other (specify):……………………………………………………………………………………………………………….

**Normal and foreseeable conditions of contact (duration and temperature)**

Specify………………………………………….……………….……………………………………………………………………………………

……………………………………………………….……………………………………………………………………………………………………

**Maximum ratio (surface area in contact with the foodstuff) / (volume/weight of the foodstuff) used to establish the compliance of the material or article:**

 6dm²/kg of food

 Other: ............................................................

**Regulatory references**

The material and/or article covered by this declaration complies with the relevant requirements of the Framework Regulation (EC) No 1935/2004, and of the Regulation (EC) No 2023/2006 (and any other relevant legislation). Any material or article falling within the scope of Regulation (EU) No 2024/3190 complies with the requirements thereof.

*List any other relevant texts by type of material and country:*

|  |  |  |
| --- | --- | --- |
| Type of material (inks, adhesives, paper/cardboard, plastic, varnishes, etc.)  n° | Regulatory texts and reference texts (resolution, recommendation, EuPIA guidelines, FEICA, authority data sheets, etc.) | Europe / Member State |
| 1 |  |  |
| 2 |  |  |
| 3 |  |  |
| 4 |  |  |
| … |  |  |

**Special materials (recycled materials, active or smart materials)**

 Not applicable…………………………………………………………………………………………………………………………………

 Regulation (EC) No 450/2009 on the presence of active or intelligent materials, specify the substance used and the number mentioned in the European register:

………………………………………………………………………………………………………….…………………………………………………

………………………………………………………………………………………………………….…………………………………………………

 Regulation (EU) No 2022/1616 on the presence of recycled materials in plastic materials and articles and attach the declaration of compliance in accordance with Regulation No 2022/1616.

…................................................................................................................................................................

…................................................................................................................................................................

 Other materials (recycled content other than plastic, etc.): ……………………………………………………………………………………………………

1. **Information relating to the material and/or article covered by the declaration**

This declaration of compliance has been drawn up on the basis of the following (tick the appropriate box(es)):

 Declarations from the raw materials suppliers (comprising the material/article)

 Overall migration analyses (if applicable, complete Table 6.1)

 Restricted substances (if applicable, complete Table 6.2)

 Information on dual-use additives (if applicable, complete Table 6.3)

 Assessment of intentionally added non-listed substances (if applicable, complete Table 6.4)

 Assessment of unintentionally added substances (if applicable, complete Table 6.5)

 Sensory test(s) (complete section 6.6)

# 6.1 Overall migration analysis

|  |  |  |  |
| --- | --- | --- | --- |
| Simulant | Duration | Temperature | Compliant / Non-compliant |
|  |  |  |  |
|  |  |  |  |

# 6.2 Information on restricted substances (purity, SML, etc. - refer to the Explanatory notes for additional information)

Specify below the substance(s) subject to restriction and the permissible limit(s)

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Names | Identification  CEE ref. or CAS number | Limits  (Specify the unit and type of limit) | Reference text | A\* | W\* | C\* | M\* |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |

\* compliance with these limits has been established by: tick the appropriate box analysis (A), worst case (W), calculation (C) or modelling (M): obligation imposed (Article 16 of Regulation (EU) No 10/2011)

If tests have been carried out, specify the simulants and test conditions:

…………………………………………………………………….……………………………………………………………………….……………..

…………………………………………………………………….……………………………………………………………………….……………..

If not completed, specify the reasons - refer to the reference documents:

………………………………………………………………………………………………………………………………………………….…………

………………………………………………………………………………………………………………………………………………….…………

**6.3 Information on dual-use additives**

 If applicable, specify the substance(s) concerned below:

|  |  |  |  |
| --- | --- | --- | --- |
| *Names* | *Identification: E number or FL number* | *CAS number* | *Concentrations used (optional)* |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**6.4 Assessment of intentionally added non-listed substances**

Risk assessment (Article 3 of Regulation (EC) No 1935/2004) carried out

 If not, list the substances and information relevant to the risk assessment

|  |  |  |  |
| --- | --- | --- | --- |
| Name | Identification  CAS - EINECS – FCM Reference No. | Reference text | Max. quantity (%) in material, packaging or article |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**6.5 Assessment of non-intentionally added substances**

 Risk assessment (Article 3 of Regulation (EC) No 1935/2004) carried out

 If not, list substances and information relevant to risk assessment

|  |  |  |
| --- | --- | --- |
| Name | Identification  CAS - EINECS – FCM Ref. No. | Comments (quantities, tests, etc.) |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

**6.6 Sensory test(s)**

 Test performed: …………………………………………………………………………………………………………………………………

|  |
| --- |
| This declaration is valid only for the material and/or article as delivered (empty packaging), and as long as there are no regulatory changes or changes that could result in a modification of material inertia and/or article inertia.  In any event, compliance shall apply only where the storage, handling and use conditions, considering the specific characteristics of the material or article, as provided for by professional practices or codes, have been observed.  **In the event of a change in the characteristics of the packaged product, its composition or its intended use, as well as in the event of a change in the conditions of use of the material and/or article, the recipient of this declaration must ensure the compatibility of the container and its contents, for which they alone shall bear responsibility.** |

Done at ………………………………………

On

*(Company signature and stamp)*