

▼B*ANNEX IV***Declaration of compliance**

The written declaration referred to in Article 15 shall contain the following information:

- (1) the identity and address of the business operator issuing the declaration of compliance;
- (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;
- (3) the identity of the materials, the articles, products from intermediate stages of manufacture or the substances intended for the manufacturing of those materials and articles;
- (4) the date of the declaration;

▼M7

- (5) confirmation that 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;

▼M19

- (6) adequate information allowing the downstream business operators to ensure compliance with this Regulation relative to the substances used for which restrictions and/or specifications are set out in Annexes I and II, including adequate information on the presence of non-intentionally added substances if present in an amount that could cause non-compliance of a final material with Article 3 of Regulation (EC) No 1935/2004.

At intermediate stages, this information shall include the identification and amount of the following substances contained in the intermediate material:

- substances that are subject to restrictions and/or specifications in Annex II, or
- substances for which genotoxicity has not been ruled out, and which originate from an intentional use during a manufacturing stage of that intermediate material and which could be present in an amount that foreseeably gives rise to an individual migration into food from the final plastic material or article exceeding 0,00015 mg/kg food;

▼B

- (7) adequate information relative to the substances which are subject to a restriction in food, 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;
- (8) specifications on the use of the material or article, such as:
 - (i) type or types of food with which it is intended to be put in contact;
 - (ii) time and temperature of treatment and storage in contact with the food;

▼M8

- (iii) 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;

▼B

- (9) 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;

▼M19

- (10) when the plastic material is a batch of material intended for reprocessing:
 - (a) the confirmation that it complies with Articles 10(1) and 10(2) of this Regulation and that it has been collected and used in accordance with point C of the Annex to Regulation (EC) No 2023/2006; and
 - (b) as appropriate, a specification of its composition and instructions for reprocessing;
- (11) when the plastic material has been manufactured with one or more substances included in the Union list of authorised substances in accordance with Article 5 of this Regulation that have been manufactured from waste, a confirmation that the substances used are compliant with point (1) of Article 8 of this Regulation.