
Changes to legislation: There are outstanding changes not yet made to Commission Regulation (EC) No 450/2009. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

ANNEX II

DECLARATION OF COMPLIANCE

The written declaration referred to in Article 12 shall contain the following information:

1. the identity and address of the business operator which issues the declaration of compliance;
2. the identity and address of the business operator which manufactures or imports the active and intelligent materials and articles, or the components intended for the manufacturing of those materials and articles, or the substances intended for the manufacturing of the components;
3. the identity of the active and intelligent materials and articles or the components intended for the manufacturing of those materials and articles, or the substances intended for the manufacturing of the components;
4. the date of the declaration;
5. the confirmation that the active or intelligent material or article complies with the relevant requirements laid down in this Regulation, Regulation (EC) No 1935/2004, and in specific Community measures applicable;
6. adequate information relative to the substances which constitute the components, for which restrictions are in place under the Community or national provisions applicable to food and this Regulation; where appropriate, specific purity criteria in accordance with the relevant Community legislation applicable to food and, the name and quantity of the substances released by the active component, to allow the downstream business operators to ensure compliance with those restrictions;
7. adequate information on the suitability and effectiveness of the active or intelligent material or article;
8. specifications on the use of the component, such as:
 - (i) the group or groups of materials and articles in which the component may be added to or incorporated into;
 - (ii) the conditions of use necessary to achieving the intended effect;
9. specifications on the use of the material or article, such as:
 - (i) the type or types of food intended to be put in contact with it;
 - (ii) the time and temperature of treatment and storage in contact with the food;
 - (iii) the ratio of food contact surface area to volume used to establish the compliance of the material or article;
10. when a functional barrier is used, the confirmation that the active or intelligent material or article complies with Article 10 of this Regulation.

The written declaration shall permit an easy identification of the active and intelligent materials and articles or the component or the substance for which it is issued and shall be renewed when substantial changes in the production bring about changes in the migration or when new scientific data are available.

Changes to legislation:

There are outstanding changes not yet made to Commission Regulation (EC) No 450/2009. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.

[View outstanding changes](#)

Changes and effects yet to be applied to :

- Annex 2 point 5 word omitted by [S.I. 2019/704 reg. 64\(a\)](#)
- Annex 2 point 6 word omitted by [S.I. 2019/704 reg. 64\(b\)\(ii\)](#)
- Annex 2 point 6 words substituted by [S.I. 2019/704 reg. 64\(b\)\(i\)](#)

Changes and effects yet to be applied to the whole legislation item and associated provisions

- s. 2 heading word omitted by [S.I. 2019/704 reg. 60](#)
- Signature words omitted by [S.I. 2019/704 reg. 63](#)
- Art. 3(g) inserted by [S.I. 2019/704 reg. 54](#)
- Art. 5(2)(b) words substituted by [S.I. 2019/704 reg. 56\(b\)](#)