



OrganiTrust®

**OrganiTrust® Plastic Food Contact
Material Products and Associated
Articles Standard**

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1. Principles of circular economy for plastic food contact materials

1.1.1. OrganiTrust[®] agrees that plastic food contact materials (FCMs) can serve a valuable purpose in ensuring food safety. However, these must fully account for and meet environmental safety requirements.

1.2. No OrganiTrust[®] approved plastic polymer, production additive or their associated degradation products may pose a risk to public health, due to the transfer of hazardous chemicals into food goods, or to the environment.

1.3. Plastic FCMs contribute significantly to the global environmental pollution crisis due to plastic waste. Plastic FCMs should therefore be used where no alternative to plastic materials is viable. Where plastic FCMs need to be used, OrganiTrust[®] approved plastic FCMs do not add to the landfill.

1.4. Sustainability aspects must be upheld wherever possible, ensuring that the production process, transport and disposal of the product meet the requirements of both the OrganiTrust[®] Standards and the statutory environmental laws and regulations in the intended market and region of production, with systems in place to mitigate and minimise any negative environmental impact caused by operations.

2. Plastic food contact material statutory regulations

2.1. Safety

2.1.1. The European Union (EU) has legislated about plastic food packaging materials through various regulations, mostly the Framework Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food, stating that 'any material or article intended to come into contact with food should be sufficiently inert to preclude substances to being transferred to food in quantities large enough to endanger human health or to bring about an unacceptable change in the composition or deterioration in its organoleptic properties'. In addition, there applies Commission Regulation (EC) No 10/2011 and its amendments in No 1282/2011 to plastic materials and articles intended to come into contact with food.

2.1.2. Compliance with this Standard will ensure compliance with current European legislative requirements for plastic FCMs, food packaging and product safety. Compliance with Article 3 of Regulation (EC) No 1935/2004 and Commission Regulation (EC) No 2023/2006 (December 22, 2006) is met as part of compliance to these Standards, applicable to all FCMs.

2.1.3. Regulation (EC) No 1935/2004 includes an annex specifically about printing inks, which has been amended to include plastic recycling processes covered by Commission Regulation (EC) No 282/2008 on recycled plastic materials and articles.

2.1.4. These Standards also conform with additional EU regulations such as Regulation 450/2009 (the 'Active and Intelligent Materials and Articles' Regulation); Regulation 1895/2005 on the use of certain epoxy derivatives; Commission Regulation (EC) No 2023/2006; and Commission Regulation (EC) No 282/2008.

2.1.5. OrganiTrust[®] certified FCMs conform to FCM regulations currently in force in the USA, which require assessments to establish that all substances used in FCMs are safe, although these regulations only apply to substances reasonably expected to migrate to food, which must be approved as an additive by either Title 21 Code of Federal Regulations, GRAS regulations or some previously sanctioned approval.

2.1.6. OrganiTrust[®] requires that any inputs of plastic FCMs intended to come into contact with food, or any substance that may migrate from FCMs, be:

- a. listed on the EU list of substances to be used in plastic food contact materials; or
- b. approved for use by the US Food and Drug Administration (FDA); and
- c. approved by the Organics Council[®].

2.2. Sustainability

2.2.1. At present, there is a lack of comprehensive EU, US or global statutory regulations on the sustainability of plastic FCMs, with minimal guidance in place in the EU, while FDA regulations currently do not cover plastic packaging waste or recycling.

2.2.2. OrganiTrust[®] standards not only conform to but surpass current statutory regulations and guidelines for sustainability, setting the global golden standard for plastic FCM sustainability.

3. Approved plastic food contact material types

3.1. Polymer types

3.1.1. High-density polyethylene (HDPE) (Type 2):

- a. chemical family: polyolefin;
- b. C.A.S. No.: 9002-88-4;
- c. formula: $(-\text{CH}_2 - \text{CH}_2 -)_n$;
- d. OrganiTrust[®] certification requires over 99 wt% pure polymer with less than 1 wt% additives;
- e. HDPE is approved for use as a plastic FCM polymer for application to both direct-contact and indirect-contact FCMs;
- f. HDPE has no hazards listed according to the Globally Harmonized System of Classification and Labeling of Chemicals (GHS).

3.1.2. Polypropylene (PP) (Type 5):

- a. chemical family: polyolefin;
- b. C.A.S. No.: 9003-07-0;
- c. formula: $(-\text{CHCH}_3 \text{CH}_2-)_n$;
- d. OrganiTrust[®] certification requires over 99.25 wt% pure polymer resin, with less than 0.75 wt% additives;
- e. PP is approved for use as a plastic FCM polymer for application to both direct-contact and indirect-contact FCMs, with both oriented polypropylene (OPP) and non-oriented PP permitted;
- f. PP has no hazards listed according to GHS.

3.2. Biodegradability

3.2.1. OrganiTrust[®] does not approve the use of biodegradable polymers (or biopolymers) for use as primary, direct-contact FCMs, as these polymers have less stability and reduced mechanical and barrier properties.

3.2.2. Plastics FCMs intended for secondary packaging purposes may be partly or fully produced using bio-based substances. Any biomaterial substances must meet all safety standards according to the Organics Council[®] approved substance list (ASL) protocol.

3.2.3. The final product labelling for biodegradable plastic tertiary FCMs must be marked as 'BIODEGRADABLE – NOT FOR FOOD CONTACT'.

4. Usage restrictions

4.1. Temperature requirements

4.1.1. Plastic FCMs should not be subject to temperatures over 60°C and are therefore unsuitable for the purpose of heating food goods.

4.1.2. Microwave heating is not permitted for any OrganiTrust[®] certified plastic FCMs.

4.2. Food goods contact requirements

4.2.1. OrganiTrust[®] does not approve the use of plastic FCMs for acidic food goods, defined as a final food good with a pH of 4.6 or below and a water activity greater than 0.85.

4.2.2. OrganiTrust[®] does not approve the use of plastic FCMs for any food goods that contain oxidising agents or any substance classed as an oxidising agent according to material safety data.

4.2.3. OrganiTrust[®] approves the use of plastic FCMs for oil-based or high-fat foods (20g/100g or more), subject to this Standard.

4.3. Polymer type restrictions

4.3.1. Where there are no readily available and accurate reverse vending systems in place to separate plastic film waste at the point of recycling, only PP polymer types are permitted for the formation of any product or packaging plastic film parts.

5. Hazard and risk assessment

5.1. Migration testing

5.1.1. Required migration tests for plastic FCMs:

- a. overall migration testing according to BS EN 1186 on plastic FCMs;
- b. specific migration testing for any substances identified by hazard and risk assessment (HRA) according to BS EN 13130 on plastic FCMs, with quantitative restrictions or specifications applicable to the substance(s) (e.g., SML, SML(T), QM, QM(T) and QMA);
- c. residual monomer testing on plastic FCMs;
- d. testing for any specified possible contaminants or non-intentionally added substances (NIAS) identified as part of the HRA and product description report (PDR). It is the responsibility of the licensee to identify any possible or probable contaminants or NIAS in the PDR and HRA, which will be verified by OrganiTrust[®] as part of the certification audit;
- e. extra attention must be paid to any potential FCM contents that may cause additional complications due to its physicochemical properties (as identified by HRA);
- f. microwave heating migration tests must be performed for all plastic FCMs that may realistically be exposed to microwaves by the end user, even though not recommended for microwave heating use, such as food storage containers. A reference method for the determination of the temperature of plastic materials and articles at the plastic/food interface exists (BS EN 14233:2002);
- g. food simulants for plastic FCM migration assessments are specified according to Council Directive 85/572/EEC and should be adhered to.

5.1.2. Approved methodology for assessment of overall migration in plastics

5.1.2.1. Overall migration (OM) represents the total amount of nonvolatile substances transferred from the FCM to the food. The OM of all chemicals that could possibly migrate during heat exposure or any other type of physical stress should be determined by a gravimetric method.

5.1.2.2. OrganiTrust[®] requires the use of standard OM testing conditions as recommended by EU Directive 10/2011. In cases where alternative testing methods are required, a full description of the requirement must be provided.

5.1.2.3. OrganiTrust[®] requires OM testing of materials to be performed with a compulsory minimum spectrum of the following simulants:

- a. simulant A;
- b. simulant B;
- c. simulant D1;
- d. Simulant C2
- e. sterilisation migration using distilled water at 120°C for two hours.

5.1.2.4. OM should be assessed according to the standard methods of BS EN 1186, using all relevant and potentially applicable FCM types.

5.1.2.5. The licensee must confirm that migration levels for all relevant substances conform to the OrganiTrust[®] general OM limits for FCM requirement of less than 0.1mg/dm²/ 0.01 mg/kg migrants transferred to a food simulant in terms of OM.

5.1.3. Prerequisite food stimulant migration testing components

5.1.3.1. Migration testing must be performed for any substances identified by the HRA which may possibly:

- a. migrate (identifying the conditions required for occurrence);
- b. be converted to a potentially migrating intermediate substance or NIAS (identifying the conditions required for occurrence);
- c. cause harm to human or environmental health upon exposure (identifying the conditions required for occurrence);
- d. cause harm to human or environmental health due to migration upon disposal (identifying the conditions required for occurrence).

5.1.3.2. Specific migration (SM) must be determined with food simulant migration data for all components that can be defined as:

- a. unreacted monomers and oligomers;
- b. metals;
- c. primary aromatic amines;
- d. plasticisers;
- e. antioxidants;
- f. heat stabilisers;

- g. slip agents;
- h. coatings and adhesives;
- i. any other component that may reasonably or potentially migrate into food goods as identified by the HRA.

5.1.3.3. OrganiTrust[®] encourages the use of standard SML testing conditions as recommended by EU Directive 10/2011. In cases where alternative testing methods are required, a full description of the requirement must be provided.

5.2. Biodegradability testing

5.2.1. Biodegradable products must be fully evaluated in terms of aerobic biodegradability and disintegration of packaging materials under controlled composting conditions:

- a. based on released carbon dioxide analysis;
- b. in an aqueous medium, based on oxygen demand in a closed respirometer system.

5.2.2. Comprehensive migration testing is required to ensure safety and stability for non-direct contact purposes or for disposable, single-use purposes.

5.2.3. Biodegradable plastic materials are not approved for direct contact purposes for any FCM that requires long-term or storage contact. They may be used for disposable, single-use FCMs and non-storage FCMs.

6. Specific product requirements

6.1. Multi-material products

6.1.1. All plastic layers in multi-material FCMs must meet the requirements established in this Standard, whether in direct contact with food goods or not.

6.1.2. Outer layers of a multi-layer plastic FCMs are still classed as being direct-contact FCMs, despite being outer layers. Only separate, detachable and removable packaging layers may be considered as secondary or tertiary outer packaging layers.

6.1.3. Adhesives, sealants, inks or any other accessory or associated component of the FCM must meet the requirements established in this Standard, using only substances approved by the Organics Council[®] and included in the ASL.

6.2. Drinking water pipe systems

6.2.1. Plastic piping systems for potable drinking water supply must meet all the requirements included in this Standard.