Explanatory notes for conformity assessments of packaging materials

(Meat and meat products)

1 Introduction

This document is intended to enable the user of food contact materials (FCM) to assess the suitability of a food contact material for its intended use as a packaging material. In addition to the legal basis, technical information and explanations are provided for the comparison of the mandatory information in a declaration of compliance of the packaging material manufacturer (or importer or distributor of packaging materials).

As a basic limitation, it must be emphasised that each foodstuff presents its own challenges when it comes into contact with the packaging material. The characteristics of a foodstuff, e.g. low pH value, high fat content, long best before date (BBD), storage temperature, oxygen tolerance, modified atmosphere packaging (MAP) and/or the thermal treatment of packaged products (e.g. pasteurisation) are decisive for the suitability or selection of a packaging material. The basic responsibility for the specific suitability of the packaging material lies with the food manufacturer. Close coordination is therefore required between the food manufacturer and the packaging material supplier. Only in this way can the manufacturer assess the suitability of the respective packaging material for his products.

The guidelines are limited to this packaging material due to the extensive individual legal measures for plastics.

Regulation (EU) No 10/2011 "Plastics Regulation" applies to food contact materials and articles according to its scope:

- Intermediate plastic materials (e.g. resins and films for further transformation) and those that are already present in the final composition but still require mechanical transformation without changing the formulation in order to achieve their shape as a finished article (e.g. thermoformable sheets and preforms for bottles);
- finished food contact materials or articles that may come into contact with food (e.g. packaging material, containers for storing food, kitchen utensils or kitchen appliances, plastic parts in food processing machines, surfaces for food preparation, inner surfaces of refrigerators, baking trays);
- Prefabricated plastic parts of finished food contact materials or articles that only need to be assembled or mounted, either during packaging/filling or before, to produce the finished article (e.g. bottle and cap, bowl and lid, parts of kitchenware or food machinery);
- Plastic layers in finished multilayer composites.

The Plastics Ordinance does not apply to:

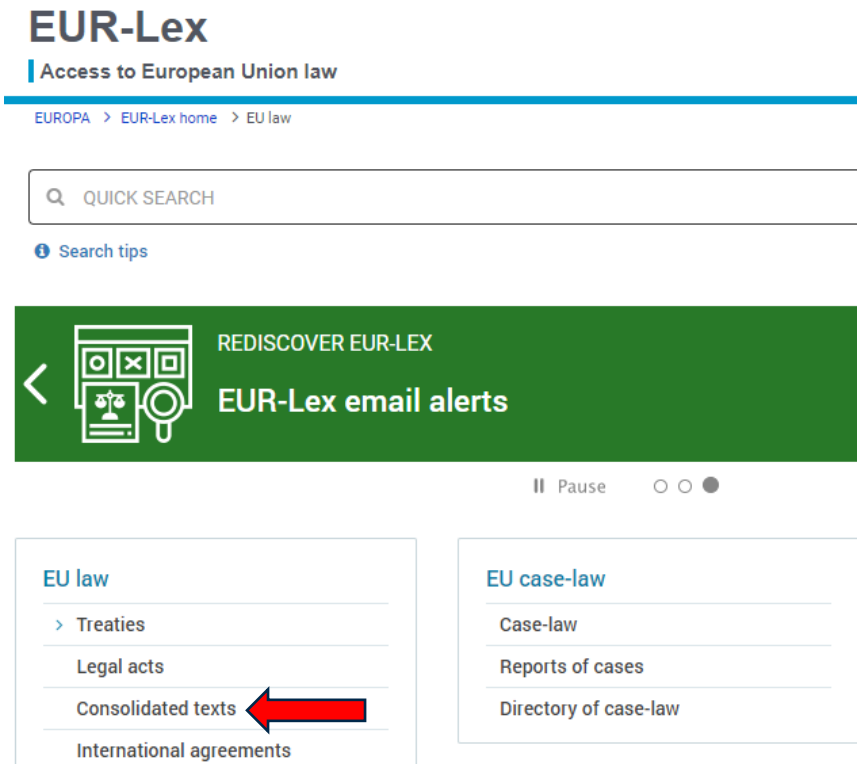
- Cellophane films, with or without lacquer coating,
- Rubber,
- Paper and cardboard, modified by the addition of plastic or not,
- Surface coatings from:
  - Paraffin waxes, including synthetic paraffin waxes and/or microcrystalline waxes,
  - Mixtures of the waxes mentioned in the previous indent with each other and/or with plastics,
- Ion exchange resins,
- Silicones.

For other FCM, e.g. paper, cardboard and paperboard, declarations of safety apply on the basis of other legal principles, which must also be assessed (e.g. BfR recommendations).

2 Find the current legal basis

The manufacturer of FCM is always obliged to fulfil the "Regulation on materials and articles intended to come into contact with food (**Regulation (EU) No 1935/2004**)". This regulation represents a binding framework for the packaging manufacturer. This includes compliance with specific measures for certain materials, authorisation of substances, ensuring traceability, inspections by the authorities and possible sanctions. The Commission regularly publishes the supplementary regulations in the Eur-lex legal information system; the current version is available at https://eur-lex.europa.eu/).

The specific supplementary regulations are to be used as a legal source. However, this is difficult for the user to read because only the amendments are listed. Our recommendation is therefore to look for a consolidated act, which is not the legal basis but is much easier to understand. The consolidated act can be accessed via the Eur-Lex website by clicking on "Consolidated texts" in the „Menu":



The desired prescription is then entered in the "Quick search" in the following manner:

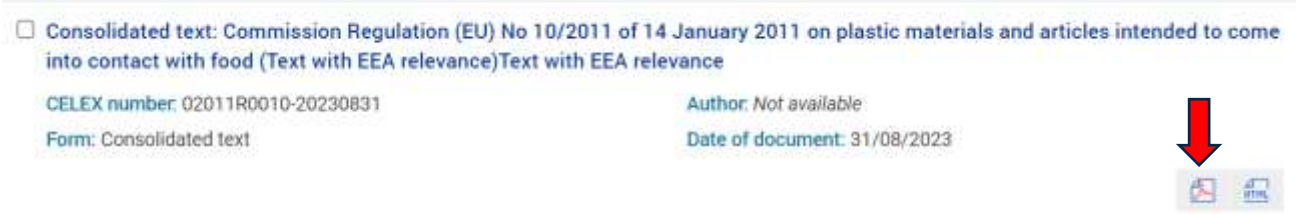
0XXXXrXXXX

Zero Year of regulation r = Regulation and publication number with four digits (fill in with 0)

Example: 02004r1935

In our example, there is a consolidated legal file from March 2021, which can be conveniently downloaded as a PDF:

In addition to this regulation, the packaging manufacturer must comply with a further framework regulation on good manufacturing practice for FCM (**Regulation (EC) No 2023/2006**). The food manufacturer does not necessarily have to be familiar with either regulation. Mentioning them here provides an overview. As an individual measure, manufacturers of plastics must comply with "Commission **Regulation (EU) No 10/2011** of 14 January 2011 on plastic materials and articles intended to come into contact with food". The consolidated legal act is currently available from 31/08/2023:



For plastic packaging materials that are intended to come into contact with food (direct food contact), the packaging manufacturer or the importer or distributor of packaging materials must provide an updated declaration of compliance. As a food manufacturer, you have the task of evaluating these, which is why the consolidated legal acts of **Regulation (EU) No 10/2011** is important.

3 Evaluation of the declaration of conformity

The declaration of conformity according to **Regulation (EU) No 10/2011** contains mandatory information according to **Annex IV**, which the packaging manufacturer must provide. Unfortunately, not all declarations of compliance have a standardised structure, so it is often necessary to search for the relevant information. We have developed a sample checklist as an appendix to the guidelines, which you can use to verify the assessment. Please also note the tips below, as the checklist assessment can be time consuming.

The assessment is explained from the perspective of the food manufacturer in relation to its own commitment and the questions asked in audits.

Requirements for the declaration of conformity	Explanation of the valuation. Please check whether ...	Check
1. Identity and address of the company issuing the declaration of conformity	... the name of the company also matches your supplier of the packaging material. Is the source of supply the same as the issuing company. How can you prove that the material you are using comes from this manufacturer (or retailer)? The address/address must also be available.	✓ Heading with reference to declaration of conformity ✓ Identity and address of the company issuing the KE ✓ Legally binding signature of the issuer (at the end of the declaration)
2. The identity and address of the company that **manufactures or imports** the plastic materials or articles *(or products from intermediate stages of their manufacture or substances)* (*intended for the manufacture of these materials and articles*)	... the manufacturer or importer is also named and addressed. This may be the same company as in the first point. This is not necessarily always the case with retailers. The legislator is concerned here with a clear reference for traceability. As a food manufacturer, you will not use any intermediate products or substances, which is why we have italicised this passage. Declarations of compliance must be passed down the chain, which is why the preliminary stage is also taken into account here.	✓ Identity and address of any other manufacturers or importers
3. Identity of the materials *and* **articles** (*products from intermediate stages of manufacture or substances intended for the manufacture of these materials and articles*)	... the designation of the material or object on the declaration of conformity can be assigned. Please also ensure that there is a clear link to the article. What designation does the exhibitor use? What identification can you find on your packaging materials in the warehouse or on your order? If the declaration of conformity confirms the conformity of a product group, how do you prove that your article falls within this group?	✓ Clear allocation of the packaging material
4. Date of the declaration	... whether the date of issue is also current. There is an unwritten "convention" that declarations of conformity can be valid for three years. But how do you assess whether or not the latest update of on Regulation on plastic materials (here: August 2023) requires an amendment to the declaration? Of course, not every additional regulation necessarily requires a new declaration from the manufacturer. On the one hand, this was not yet available at the time the packaging material was produced and packaging material may always be used up. Secondly, the changes may not be relevant to your packaging material. Only your supplier can help you here, as they will be able to assess the relevance. They will either issue a new declaration or inform you that a new declaration is not necessary.	✓ Current date of issue

Requirements for the declaration of conformity	Explanation of the valuation. Please check whether ...	Check
5. Confirmation that the **plastic materials or articles** (*the products from intermediate stages of manufacture or the substances*) fulfil the relevant requirements laid down in **Regulation (EU) No 10/2011** and in Article 3, Article 11(5), Article 15 and Article 17 of **Regulation (EC) No 1935/2004**	... there is a list of the legal bases in the declaration of conformity. This is usually the case. Unfortunately, there are also stumbling blocks here. In addition to the regulations, some manufacturers also list all supplementary regulations. This is difficult to check and a supplementary regulation is often forgotten ... It is better to list the legal basis with the reference "in the current version". In conjunction with the date of the declaration, it is possible to recognise that it is up to date. Please also check whether the packaging manufacturer can also provide further (legal) bases. Depending on the other materials, these may be recommendations from the *Federal Institute for Risk Assessment* (BfR) or, depending on the country of distribution, laws from other countries such as the USA (see 5 tips). This would not be a legal obligation for your supplier, but a possible customer request. **Regulation (EC) No 1935/2004** • Art. 3 - General requirement of good manufacturing practice • Art. 11(5) - Community authorisation - Information on new scientific and technical information • Art. 15 - Labelling of the material • Art. 17 - Traceability via unique identification	✓ Reference to legal principles ✓ Suitability for food contact
6. Sufficient information on the **substances used or their degradation products** for which Annexes I and II of **Regulation (EU) No 10/2011** contain restrictions and/or specifications so that downstream operators can also ensure compliance with these restrictions	... whether Annexes I and II have been observed by the packaging manufacturer. According to the Union list (Annex I), only these substances may be used in the manufacture of plastics. It is possible that specific migration limits (SMLs) apply here. In this case, the packaging manufacturer must list these and declare that the legal basis is fulfilled. This is often done in the form of a table. For example, Regulation **(EU) No 10/2011** has set an SML of 15 mg/kg food or food simulant for caprolactam (starting material for polyamide). Annex II lists special instructions that the packaging manufacturer must observe for migrations of substances. SMLs must also be taken into account here. These annexes primarily provide information on which substances must be analysed in a compliance test depending on the source materials in order to comply with the regulation. Sending a migration analysis itself is not mandatory for the packaging manufacturer.	✓ Indication of substances used ✓ Information on SML, if applicable ✓ Information on NIAS, if applicable

Requirements for the declaration of conformity	Explanation of the valuation. Please check whether ...	Check
	However, all necessary data should be recognisable from the declaration of compliance. Furthermore, the presence or absence of undesirable or non-intentionally added substances (NIAS) must be assessed by the packaging manufacturer. There should also be a reference to this in the declaration. NIAS = non-intentionally added substances are all substances unintentionally present in the end product, whether due to impurities in starting materials, side reactions during polymerisation, degradation products of stabilisers or contamination due to improper storage. These substances must be subjected to a risk assessment in the same way as the intentionally contained, i.e. known substances. There is currently no standardised, clearly defined procedure for this in the EU, meaning that an individual approach is used in each case.	
7. Sufficient information on the **substances whose use in food is restricted** (*obtained from experimental data or theoretical calculations on their specific migration levels 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 legislation or, in the absence thereof, with national food legislation	... there is an indication of so-called dual use substances. There are excipients that can be used both in food as food additives and as excipients in FCM. For these dual-use substances, the lowest limit from the two regulations applies in the end product. In order for you to know whether dual-use substances are present, the declaration of compliance from the packaging manufacturer must state whether they are present in the product.	✓ Information on dual-use additives
8. Specifications for the use of the material or object, e.g: • Type or types of food that should come into contact with it; • Duration and temperature of treatment and storage in contact with the food; • Ratio of the surface area in contact with food to the volume used to determine the conformity of the material or article;	... there is an indication of which foods may come into contact with the FCM. The type of food is often linked to the contact temperature, e.g. "*Intended for single contact with food. The product is suitable for the intended contact with aqueous, acidic, alcoholic and fatty foods.* *Any long-term storage at room temperature (max. 40 °C) or below, including heating to 70 °C for up to 2 hours or heating to 100 °C for up to 15 minutes. Freezable down to -20 °C"* Are there any restrictions on the use of the packaging material (e.g. *"not suitable for fatty foods"*)? The manufacturer or distributor ofFCM is happy to provide storage instructions. These apply to the storage of the LMKM and not in connection with the food. As the storage limits are often very narrow, e.g. 20 °C storage temperature, clarify the conditions under	✓ Type(s) of foodstuff(s) for which the packaging is suitable ✓ If applicable, clear information on restrictions on use ✓ Duration, temperature of treatment and storage in contact with food ✓ Storage condition of the packaging material ✓ Indication of food ratio

Requirements for the declaration of conformity	Explanation of the valuation. Please check whether ...	Check
	which you store the LMKM in your own company. It may well be that they change at excessively high temperatures and are no longer suitable, e.g. shrink film. For this reason, this note must also be checked and adjusted. In the ordinance, the legislator states that substances can migrate from the LMKM. In addition to the SML, the sum of all migration values = global migration also applies. Global migration, also known as OM = overall migration, is a measure of the inertness of materials and has a migration limit of 60 mg per kilogramme of food. This must also be confirmed. The challenge lies with foods whose surface-to-volume ratio cannot be represented by the cube. The packaging manufacturer must determine the specific migration values expressed in mg/kg using the actual surface area to volume ratio for the actual or intended use in order to verify compliance. The area of application of the food contact material must be compared with its own uses. **Regulation (EU) No 10/2011** specifies simulants that should reflect a foodstuff (see Annex Table 1-3).	
9. If a functional barrier is used in a multi-layer material or article: Confirmation that the material or article complies with the provisions of Article 13(2), (3) and (4) or Article 14(2) and (3) of **Regulation (EU) No 10/2011**	... the declaration provides information on the different layers of the packaging material, e.g. type of material and structure of the layers. The type of barrier layer must be identifiable. In addition, the following items should be confirmed: **Regulation (EU) No 10/2011** • Art. 13 para. 2, 3 and 4 - certain substances may not be used. The FCM must not contain any substances that are classified as "mutagenic", "carcinogenic" or "toxic to reproduction". • Art. 14 para. 2 and 3 - Exemptions if there is no direct contact.	✓ Information on functional barriers for (multilayer materials)

4 Procedure for deviations / questions

There will always be times when you find discrepancies in the assessment of your declaration of conformity. There may be various reasons for this. Therefore, the first recommendation is to collect the questions. Firstly, go through the entire declaration of conformity. Then write to the author of the declaration to get the answer or an amendment. Always include the legal basis in this list. It is best to send the page on the structure of the declaration of conformity from Regulation (EU) No 10/2011 in the relevant language. This will make the manufacturer more aware that you have familiarised yourself with the technical background.

It may be necessary to involve other experts in order to clarify issues. The Federal Institute for Risk Assessment should be mentioned first and foremost, and the laboratories involved second. Be prepared for the fact that you will not receive an immediate answer, but if you can prove in the audit that the declarations have been checked and the change has been queried, you have already gained a lot.

You should always prove that the FCMare suitable for the intended use. It is crucial that the types of food and the area of application are correct in terms of temperature. High temperatures in particular can lead to increased migration. If this is not included on the declaration, it must be added more quickly than any other missing information.

The validity of the declaration of conformity also often raises questions. In principle, this is not defined, but rather a consideration with regard to relevant changes. As a rule, we assume that nothing has changed within three years. If a legal amendment has been made during this time, ask your supplier whether they see the need for a prompt update. In principle, they may continue to market LMKM manufactured in accordance with the old legislation until the transitional period expires.

5 Abbreviations

FCM	Food contact materials
BBD	Best before date
BfR	Federal Institute for Risk Assessment
SML	specific migration limits (specific migration limit)
NIAS	non intentionally added substances
OM	overall migration (global migration)

6 Annex

Table 1: List of food simulants according to **Regulation (EU) No 10/2011 Annex III**

Food simulant	Abbreviation
Ethanol 10 % by volume	Food simulant A
Acetic acid 3 % by weight	Food simulant B
Ethanol 20 % by volume	Food simulant C
Ethanol 50 % by volume	Food simulant D1
Vegetable oil (1)	Food simulant D2
Poly(2,6-diphenyl-p-phenylene oxide), particle size 60-80 mesh, pore size 200 nm	Food simulant E

Table 2: Classification of food simulants by food category according to **Regulation (EU) No 10/2011 Annex III** (extract)

Reference number	Name of the foodstuff	Food simulants					
		A	B	C	D1	D2	E
06.03	Meat of all zoological species (including poultry and game):						
	A. Fresh, chilled, salted, smoked	X				X/4(**)	
	B. Processed meat products (e.g. ham, salami, bacon, sausage and others) or in the form of paste, creams	X				X/4(**)	
	C. Marinated meat products in an oily medium	X				X	

Reference number	Name of the foodstuff	Food simulants					
		A	B	C	D1	D2	E
06.04	Preserved meat:						
	A. In fatty or oily medium	X				X/3	
	B. In aqueous medium		X (*)		X		
08	**Miscellaneous products**						
08.02	Fried or roasted foods:						
	A. Fried potatoes, fritters and the like	X				X/5	
	B. Of animal origin	X				X/4	
08.03	Preparations for soups, broths, sauces, in liquid, solid or powder form (extracts, concentrates); homogenised composite food preparations, prepared dishes including yeast and raising agents:						
	A. Powdered or dried:						
	I. With fatty character					X/5	
	II. Other						X
	B. any other form other than powder or dried:						
	I. With fatty character	X	X (*)			X/3	

Reference number	Name of the foodstuff	Food simulants					
		A	B	C	D1	D2	E
	II. Other		X (*)	X			
08.04	Sauces:						
	A. with aqueous character		X (*)	X			
	B. With fatty character e.g. mayonnaise, sauce, derived from mayonnaise, salad creams and other oil/water mixtures e.g. coconut based sauces	X	X (*)			X	
08.06	Sandwiches, toasted bread pizzas and the like containing any kind of foodstuff:						
	A. With fatty substances on the surface	X				X/5	
	B. Other						X
08.09	Frozen or deep-frozen foods						X

For testing migration from materials and articles not yet in contact with food, the food simulants corresponding to a specific food category are selected according to Table 2 below.
For testing the overall migration from materials and articles intended to come into contact with different food categories or a combination of food categories, the classification of food simulants under point 4 shall apply.
Table 2 contains the following information:
Column 1 (reference number): contains the reference number of the food category.
Column 2 (name of the food): contains a description of the food belonging to the food category.
Column 3 (food simulant): contains sub-columns for the individual food simulants.
The food simulant marked with an "X" in the corresponding sub-column of column 3 is used to test the migration of materials and articles that are not yet in contact with food.
For food categories where in sub-column D2 the character 'X' is followed by a number separated by a slash, the result of the migration test shall be divided by that number before the result is compared with the migration limit. The number shall be the correction factor referred to in point 4.2 of Annex V to this Regulation.
In food category 01.04, the food simulant D2 is replaced by 95% ethanol.
For food categories in which the "X" symbol is followed by "(*)" in sub-column B, the test in food simulant B can be omitted if the food has a pH value of more than 4.5.
For food categories where the "X" symbol is followed by "(**)" in sub-column D2, the test in food simulant D2 may be omitted if it can be demonstrated by a suitable test that there is no contact between fat and plastic food contact material.

Table 3: Standard test conditions according to **Regulation (EU) No 10/2011 Annex V**

Test no.	Contact time in days [d] or hours [h] at contact temperature in [°C]	Intended food contact conditions
OM 1	10 d at 20 °C	Any food contact at frozen and refrigerated conditions
OM 2	10 d at 40 °C	Any long-term storage at room temperature or below, including heating up to 70°C for up to 2 hours, or heating up to 100°C für up to 15 minutes.
OM 3	2 h at 70 °C	Any contact conditions that include heating up to 70 °C for up to 2 hours or heating up to 100 °C for up to 15 minutes, which are not followed by long term room or refrigerated temperature storage.
OM 4	1 h at 100 °C	High temperature applications for all food simulants at a temperature up to 100 °C.
OM 5	2 h at 100 °C or at reflux or alternatively 1 h at 121 °C	High temperature applications up to 121 °C.
OM 6	4 h at 100 °C or at reflux	Any food contact conditions with food simulants A, B or C at temperatures exceeding40 °C.
OM 7	2 h at 175 °C	High-temperature applications with fatty foods exceeding the conditions of OM 5.

Test OM 7 also covers the food contact conditions described for OM 1, OM 2, OM 3, OM 4 and OM 5. It represents the most unfavourable conditions for fat-containing food simulants in contact with non-polyolefins. If it is not technically possible to perform OM 7 with the food simulant D2, the test according to paragraph 3.2 can be substituted.
Test OM 6 also includes the food contact conditions described for OM 1, OM 2, OM 3, OM 4 and OM 5. It represents the most unfavourable conditions for food simulants A, B and C in contact with non-polyolefins.
The OM 5 test also covers the food contact conditions described for OM 1, OM 2, OM 3 and OM 4. It represents the most unfavourable conditions for all food simulants in contact with polyolefins.
The OM 2 test also covers the food contact conditions described for OM 1 and OM 3.