

EU food contact regulations for safe food processing

- Do you know the differences between EC 1935/2004 and 2002/72/EC, and EU 10/2011?
- Do you understand what *overall migration* means?
- Are you aware that every belting product needs its own certificate for direct food contact?

If you are unsure about the answers, you can find them all in this leaflet. It covers the most important issues regarding regulations about food contact materials in the European Union on processes where plastic materials are used. The information is valid for all belt products in direct contact with foodstuffs – whether fabric-based conveyor belts, plastic modular belts, plastic chains, and round or timing belts.

Habasit knows the law

Habasit has always respected the laws on food conveyor and processing belts, and keeps fully up-to-date with all current requirements. Regardless of where a belt application takes place, we ensure that the EU regulations in force for the product are met.

Legal harmonization

The directives and regulations in force within the European Union and its member states can be demanding and are not always easy to understand. To simplify matters, the EU started to harmonize legislation on food contact materials several years ago. Currently, harmonized legislation only exists for a few materials. Legislation on ceramics, plastics and regenerated cellulose can be considered complete, while other areas are pending and further developments are expected.





EU food contact regulation – for safe food processing

EU regulations and directives

The legal basis for the enactment of regulations is Article 288 of the *Treaty on the Functioning of the European Union*. It says:

“A **regulation** shall have general application. It shall be binding in its entirety and directly applicable in all Member States.” Therefore, after enacting a regulation it comes into force immediately throughout the entire EU.

“A **directive** shall be binding, as to the result to be achieved, upon each Member State to which it is addressed, but shall leave to the national authorities the choice of form and methods.” This means that a directive needs to be implemented into national legislation before it can come into effect in each member state, which is why sometimes reference is made to national legislation.

Three main documents

For the food processing industry, when doing business in the European Union there are three main documents to be considered:

- “Framework” Regulation EC 1935/2004
- Regulation EC 2023/2006 on good manufacturing practice
- Regulation (EU) No. 10/2011 - “Plastic implementation measure” PIM

“Framework” Regulation EC 1935/2004

One of the most important regulations is Regulation (EC) No 1935/2004, which applies to all food contact materials (FCM). It contains definitions, restrictions and requirements, including:

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|------------|--|
| Article 3 | General safety: Must not endanger human health No unacceptable change in the composition No deterioration of organoleptic characteristics |
| Article 4 | Active and intelligent materials may be used |
| Article 6 | Member states may maintain or adopt national provisions |
| Article 15 | Labeling of food contact materials |
| Article 16 | Declaration of compliance towards customer Supporting documentation: demonstrating compliance available on demand to the authorities |
| Article 17 | Traceability: ability to follow a material or article through all stages of manufacture, processing and distribution: <ul style="list-style-type: none"> • one step forward and one step back • must be available within four hours • in force since October 27, 2006 |

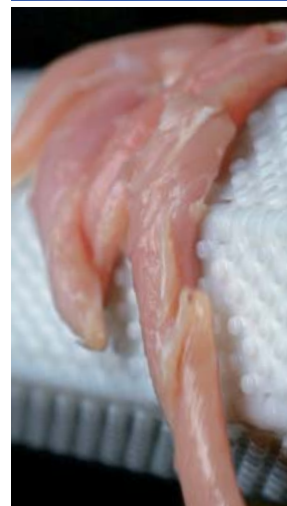
In Annex 1 of this regulation, 17 groups of materials and articles are listed that may be covered by specific measures. One of these – plastic materials – is valid for plastic belting products.

Regulation EC 2023/2006 on good manufacturing practice

Regulation EC 2023/2006 describes good manufacturing practice (GMP) for materials and articles intended to come into direct contact with food. The manufacture of such materials must comply with these regulations, so that the materials do not represent a danger to the consumer, nor change the composition of food or its organoleptic characteristics.



| | |
|------------------------|---|
| Polyacetal POM | ✓ |
| Polyamide PA | ✓ |
| Polyester PET | ✓ |
| Polyolefine TPO | ✓ |
| Polyurethane TPU | ✓ |
| Polyurethane PUR | ✓ |
| Polyvinyl-chloride PVC | ✓ |
| Fluorpolymer FP | ✓ |



Manufacturers must establish a quality assurance system and a quality control system. Their personnel's knowledge and skills, the organization of the premises, and their equipment must ensure compliance of the finished articles with the rules.

Continuous maintenance of documentation is required for:

- Specifications
- Manufacturing formulae
- Product processing

Regulation (EU) No. 10/2011 - "Plastic implementation measure" PIM

Regulation (EU) No. 10/2011, in force since May 1, 2011, is the replacement of Directive 2002/72/EC, commonly called the "Plastics Directive".

This is a specific measure within Regulation (EC) No 1935/2004, which has immediate legal force in all member states. There are various transitional provisions for this new regulation, and migration testing and supporting documents are needed. However, Declarations of Compliance based on the "old" rules according to Directive 2002/72/EC remain valid until December 31, 2015. So for conveyor belt users, no change of behavior is required immediately.

Both Directive 2002/72/EC as well as Regulation (EU) No. 10/2011 establish:

- A complete *Positive List* of monomers, additives and other starting substances that can be used in food contact plastic production
- Requirements, e.g. Overall Migration Limit, Specific Migration, etc., that the finished article must meet when tested with appropriate food simulants related to real use conditions

The Overall Migration Limit (OML) is usually fixed at 10 milligrams per square decimeter of the article (or 60 mg/kg). The directive also defines the Specific Migration Limit (SML) and the Maximum Quantity allowed (QM) for some specific substances.

Accordingly, all monomers and additives intended for use in the production of food contact plastics must be listed in Regulation (EU) No. 10/2011 just as they were previously in Directive 2002/72/EC. The final food contact article must meet the OML and any specifications that have been established for substances used as components of the article.

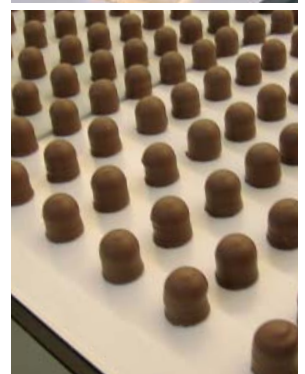
The steps needed to define a plastic article are:

- Evaluation of compliance with legislation on all additives, monomers, and starting substances
- Evaluation of any starting substances for which additional limitations are fixed
- Test of Overall Migration on finished article
- Inspection and test of compliance with established limitations (SML or QM)

All this needs to be done and documented by the manufacturer of plastic materials and articles.

What Habasit does for its customers

Habasit maintains an active good manufacturing practice (GMP) process for the production and fabrication of our food belts. Habasit's food processing and conveyor belts and their accessories, such as profiles, only use materials that conform with EU legislation. All are tested thoroughly in line with the requirements. We provide our customers with the appropriate Declarations of Compliance (DoC). Our product data sheets also clearly show the food contact status of belts and accessories. Furthermore, our R&D and manufacturing teams ensure constant follow-up and updates on changing requirements.



Declaration of Compliance (DoC)

Conformity with valid EU regulations is a precondition for materials and articles used for direct food contact. The DoC accompanies the material or article and mentions the intended conditions of use. It carries an issue date and contains all the information needed to identify both the material or finished article as well as its manufacturer.

The declaration mentions the relevant directives and legal regulations, and gives information on substances used that are subject to limitations or specifications for food. The legislation does not include an expiration date for DoCs, but they must be updated in case of material or process modifications, or if legislative changes require an adaptation. Our DoCs are available online at www.habasit.com/en/food-certificates-doc.htm.

Belt user's responsibility

EU food producers and food processing equipment manufacturers (OEMs) using plastic conveyor belts in direct food contact, or distributors selling belts intended for direct food contact, are legally required to prove EU conformity of the belts. This evidence is fully provided through the DoC.

The DoCs provide clear information about the food types, time and temperature conditions allowed for the declared item. Specific migration values and test results are not part of a DoC, but can be reviewed by competent authorities in case of an incidence.

Industry standards


There are several industry standards on quality systems that food manufacturers must meet. None of these standards require more than compliance with EU food contact regulations on equipment, and as a result, a DoC for belts is perfectly acceptable.

Summary

- EU regulations focus on raw materials and the migration from articles in direct contact with food
- Manufacturers are required to record their processes and document conformity to the rules
- They must provide this data to the authorities on request
- Manufacturers are also required to provide their customers with a Declaration of Compliance (DoC)
- The DoC contains all the data required to identify a material or article, and gives information on any limitations of use if applicable
- Such a DoC is needed by food processors to prove the suitability of the intended use of the material
- Habasit food belts intended for use in the EU comply with all valid legislation
- They usually also conform with US regulations from the FDA and USDA

For more detailed information, see the website of the European Union:

http://ec.europa.eu/food/food/chemicalsafety/foodcontact/index_en.htm or the legislation section at: <http://eur-lex.europa.eu>.

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|--|---|
| <p>Habasit AG Power transmission and conveyor belts Römerstrasse 1 CH-4153 Reinach Tel: +41 61 715 15 15 Fax: +41 61 715 15 55 www.habasit.com</p> |  |
| Declaration of Compliance | |
| <p>This declaration of compliance relates exclusively to the product specified herein in the state in which it was placed on the market. Any components added, handling effected or modifications carried out subsequently are expressly excluded. The present declaration ceases to be valid in the event that the use of the product is not in conformance with the conditions specified in the applicable regulations, if any, and in Habasit's technical documentation. The product is intended for repeated use only.</p> | |
| <p>Herewith we declare that the product specified herein is in compliance with the following food contact regulations.</p> | |
| FAS-8EICT-U1 | |
| EU | |
| <p>Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food as amended. Regulation (EC) No 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food as amended. This material has been manufactured in accordance with the relevant requirements of that regulation. Regulation (EU) No 10/2011 relating to plastic materials and articles intended to come into contact with foodstuffs as amended.</p> | |
| <p>This product meets the relevant requirements of Regulation (EU) No 10/2011 as amended and is applicable for direct contact with:</p> | |
| <p>- dry, aqueous, acidic, alcoholic and fatty or oily food types according to Annex III, table 2 - up to 30 minutes contact time at up to 80 °C</p> | |
| <p>The raw materials used comply with the requirements of this regulation as amended.</p> | |
| <p>This product does not bring about an unacceptable change in the organoleptic properties of food.</p> | |
| <p>Above mentioned product does not contain dual use additive(s) acc. to Regulation (EC) No 1333/2008 (food additives) and Regulation (EC) No 1334/2008 (flavourings) in their current version.</p> | |
| <p>Testing of overall migration, specific migration and other applicable restrictions (maximum permitted quantity, primary aromatic amines, etc.) was performed according to Directive 85/572/EEC as amended, Directive 82/711/EEC as amended and the provisions of Directive 2002/72/EC as amended.</p> | |
| <p>Ratio of food contact surface area to volume used to establish the compliance of the article: 6</p> | |
| <p>Food simulants and migration conditions used for migration tests:</p> | |
| <p>- B (3% acetic acid) 30 min. at 80°C - C (10% Ethanol) 30 min. at 80°C - D (olive oil) 30 min. at 80°C</p> | |
| <p>Declaration of Compliance FAS-8EICT-U1</p> | <p>30.10.2013 1 / 2</p> |

Glossary

| | |
|-------------------|---|
| Article | An article (food contact article) is the finished film, bottle, dough hook, tray, or – in our case – conveyor and processing belt or accessory manufactured out of food contact material. |
| Directive | Directives must be implemented into national legislation before coming into force. |
| EC | The European Communities (also European Community or EC) were three international organizations: the European Coal and Steel Community (ECSC), the European Economic Community (EEC) and the European Atomic Energy Community (EAEC or Euratom). |
| EU | The European Union (EU) is the economic and political union of 27 member states (in 2011) located primarily in Europe. The EU was formally established when the Maastricht Treaty came into force on November 1, 1993. After the Treaty of Lisbon, the legal personality of the European Community (EC) was transferred to the newly consolidated EU, abolishing the European Communities. |
| FCM | Food contact materials (FCM) are all materials intended to come into direct contact with foodstuffs, including packaging materials, but also cutlery, dishes, processing machines, containers, etc. The term also includes materials that are in contact with water intended for human consumption. FCM is often a mixture of single substances such as an antioxidant in a polymer. |
| FDA | The US Food and Drug Administration, but also the synonym for the regulation of food contact materials in the United States. Not valid for the European Union. |
| GMP | Good manufacturing practice is the process used to maintain food safety by applying best practices, documentation and continuous improvement. Required by EU regulations for food processors and for the production of food contact material suppliers. It is close to the ISO 9000 approach. |
| HACCP | Hazard Analysis and Critical Control Points is a concept for improving food safety in the manufacturing process. HACCP was conceived in the 1960s when NASA asked the Pillsbury Company to manufacture the first space food with 100% security. Belts can be part of a control point, but as HACCP is a process and not a specification, there are no requirements on conformity for any items (equipment, raw materials, belts, etc.). |
| Migration | Migration describes the concentration-driven movement (flux) of substances (molecules) in a matrix. Related to food contact materials, this means that substances, monomers and/or additives contained in the food contact material (high concentration) tend to flux into the food in contact with this material (low concentration). |
| Regulation | Regulations come into force immediately and do not require implementation into national legislation. |
| USDA | The United States Department of Agriculture, but also the synonym for the application of a specific approved list of equipment for meat and poultry and dairy processing in the United States. Not valid for the European Union. |

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Rossi is one of Europe's largest manufacturers of gear reducers, gearmotors, inverters, standard and brakemotors, and is a member of the Habasit Group.

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Subject to alterations
Printed in Switzerland
Publication data:
2151FLY.FOD-en1113HQR

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