

**CODE FOR GOOD MANUFACTURING PRACTICES FOR
THE EUROPEAN ALUMINIUM INDUSTRY**

**Good Manufacturing Practices for
aluminium alloy semi and end products
intended to come into contact with
foodstuff**

Review of April 2012

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1. Scope of the document

This code is developed in line with art. 3a of “EU Regulation 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food”, and applies to the manufacture of aluminium and aluminium alloy semi-products and end products intended to come into contact with foodstuff. Any further processing of these products, including packing or filling, shall be covered by a separate Good Manufacturing Practice document.

2. Legal and other references

The compliance of food contact materials should be demonstrated in the following order of preference/priority:

1. EU Legislation (Regulations, Decisions and Directives) and national legislation resulting from their transposition.
2. Where EU legislation is incomplete, relevant national legislation of EU/EFTA member states as well as other relevant national legislation.
3. Standards, guidelines, recommendations and codes of practice

2.1. EU Legislation

The legal EU reference for these Good Manufacturing Practices is based on the EU Framework Regulation 1935/2004 on materials and articles intended to come into contact with food, and EU Regulation 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food.

Article 3 of EU Regulation 1935/2004 describes the objective for materials and articles intended to come into contact with food:

Materials and articles must be manufactured in compliance with good manufacturing practice so that, under their normal or foreseeable conditions of use, they do not transfer their constituents to foodstuffs in quantities which could:

- *endanger human health*
- *bring about an unacceptable change in the composition of the foodstuffs*
- *or a deterioration of the organoleptic characteristics thereof.*

EU Regulation 2023/2006 applies to all sectors and to all stages of manufacture, processing and distribution of materials and articles, up to but excluding the production of the starting substances.

All packaging materials containing epoxy components shall comply with Commission Regulation (EC) 1895/2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food.

EU Regulation 10/2011 and its amendments, repealing Directive 2002/72/EU and its amendments, is not directly applicable to aluminium in contact with foodstuff. Nevertheless it is a reference document regarding coatings / laminate structures assessment. In fact, EU Regulation 10/2011 contains lists of substances which are fully or partly toxicologically tested according to EU guidelines.

2.2. National Legislation

In addition to the existing national legislation on general aspects related to materials in contact with foodstuff, the following national legislation contains specific requirements for aluminium in contact with foodstuff.

- **France:** French Brochure n. 1227 of JORF (Arrete of 27 August 1987 related to materials and objects in aluminium or in aluminium alloy in contact with food, products and drinks)¹.
- **Italy:** Decree 18 April 2007 n. 76, Regulations concerning the hygiene of materials and articles of aluminum and aluminum alloys intended to come into contact with food²

2.3. Standards Guidelines and Recommendations

2.3.1. Standards

The following standards contain specific relevant provisions for aluminum in contact with food:

- EN 573-3 “Aluminium and aluminium alloys - Chemical composition and form of wrought products - Part 3: Chemical composition and form of products”
- EN 601 “Aluminium and aluminium alloys – Castings – Chemical composition of castings for use in contact with food”

¹ Arrêté du 27 août 1987 relatif aux matériaux et objets en aluminium ou en alliages d'aluminium au contact des denrées, produits et boissons alimentaires

² Decreto 18 aprile 2007 n. 76, Regolamento recante la disciplina igienica dei materiali e degli oggetti di alluminio e di leghe di alluminio destinati a venire a contatto con gli alimenti

- EN 602 “Aluminium and aluminium alloys – Wrought products – Chemical composition of semi products used for the fabrication of articles for use in contact with food.”
- EN 14287 “Aluminium and aluminium alloys - Specific requirements on the chemical composition of products intended to be used for the manufacture of packaging and packaging components.”
- EN 14392 “Aluminium and aluminium alloys – Special requirements for anodized products for use in contact with food.”

2.3.2. Guidelines

The following guidelines are relevant:

- “Guidelines on Metals and Alloys used as Food Contact Materials”, Council of Europe, March 9, 2001
- French Material Specification from DGCCRF (Information Note Number 2004 – 64 and its amendments)
- “CAST Project. Guidelines for the application of the Regulation (EC) 2023/2006 to the supply chain of materials and articles intended to come into contact with food”

2.3.3. Recommendations

The following existing recommendations might be relevant:

- Opinions of Scientific Committee on Food (SCF) and of European Food Safety Agency (EFSA),
- US FDA: 21 CFR paragraphs 170 - 179

2.3.4. Codes of Practice

The following codes of practice may be relevant:

- Flexible packaging
 - “Code for Good Manufacturing Practices for Flexible and Fibre-based Packaging for Food” (FPE) - www.flexpack-europe.org
- Coatings
 - “Code of Practice for coated articles where the food contact layer is a Coating” (CEPE) – www.cepe.org
- Paper
 - “Good Manufacturing Practice for the Manufacture of Paper and Board for Food Contact” (CEPI) - www.cepi.org

All references mentioned above may not be applicable to all production stages.

3. Description of Good Manufacturing Practices versus quality management systems

The definition of good manufacturing practices is described in articles 1 and 2 of Regulation (EC) 2023/2006 as follows:

This Regulation lays down the rules on good manufacturing practice (GMP) for the groups of materials and articles intended to come into contact with food (hereafter referred to as materials and articles) listed in Annex I to Regulation (EC) 1935/2004 and combinations of those materials and articles or recycled materials and articles used in those materials and articles.

This Regulation shall apply to all sectors and to all stages of manufacture, processing and distribution of materials and articles, up to but excluding the production of starting substances.

In order to consistently implement these requirements, the procedures set out in the ISO 9000 series, or another quality management system must be used.

4. Requirements

4.1. Design for Compliance

The objective of the Framework Regulation 1935/2004 outlines the integrity of the composition of a food contact material or article. The composition of aluminium as food contact material or as component of food packaging must fulfill the requirements of EN 601 or EN 602 and EN 573-3 in order to assure the integrity in terms of health, safety and organoleptic characteristics.

Requirements differ between bare metal, surface treated, anodized, coated or converted metal products.

- **Bare metal:** fulfill requirements of Regulation 1935/2004 which is done via compliance with EN 601, EN 602 or EN 14287

and as applicable:

- **Surface treated:** safety assessed satisfying the requirements of Article 3 of EC Regulation 1935/2004.
- **Lubricated:** in compliance with

- EU Regulation 10/2011, as amended, including overall migration limits, as far as applicable
- or U.S. Food and Drugs Administration: Code of Federal Regulations Title 21, parts. 170 - 179
- or edible grade types
- or European Pharmacopoeia and SCF/EFSA opinions

- **Coated/Laminated** (where the food contact layer is a plastic material): compliance with EU Regulation 10/2011, as amended.

- **Anodized**: in compliance with EN 14392.

- **Printing inks**: in compliance with
 - Annex of EU Regulation 2023/2006

 - Council of Europe Resolution AP (2005) - 2, on packaging inks applied to the non-food contact surface of food packaging materials and articles intended to come into contact with foodstuffs

 - Council of Europe Resolution AP (89) – 1, on the use of colourants in plastics materials coming into contact with food

 - U.S. Food and Drugs Administration Code of Federal Regulations, Sec. 178.3297 - Colorants for polymers

 - EuPIA’s “Exclusion List for printing inks and related products”

 - EuPIA “Guideline on Printing Inks applied to the non-food contact surface of food packaging”

- **Coated or converted metal products**: in compliance with
 - the French “Guide of Good Hygiene Practices for Metal Packaging”

 - “Code for Good Manufacturing Practices for Flexible and Fibre-based Packaging for Food” (FPE)

 - “Code of Practice for coated articles where the food contact layer is coating” (CEPE)

During the design phase specific requirements laid down in chapter 2 of this document have to be taken into account.

4.2 Production Process

At each stage of commercial production, the integrity of the established safe composition needs to be consistently maintained. Procedures to control changes (management of change) that can alter the composition or organoleptics of the food contact material, directly or indirectly, as well as contamination prevention procedures, should be in place.

Potential composition changes outside specifications need to be flagged and a judgment – if necessary supported by new safety assessments – needs to be made to confirm continued compliance with food contact Directives and Regulations.

5. Good manufacturing Practices within the production processes

Good manufacturing practices are directed to meet the requirements of the intended use. It follows a chain starting at the casting, followed by rolling, converting and finishing processes.

The general process steps may be:

- Casting
- Hot/cold and foil rolling
- Separating
- Annealing
- Surface treatment
- Lubrication
- Coating
- Lamination
- Slitting
- Packing

The above mentioned process steps do not necessarily reflect the chronological sequence of aluminium manufacturing processes for food contact materials.

Good manufacturing practices shall be in compliance with general rules on GMP concerning quality assurance system (article 5), quality control system (article 6) and documentation (article 7).

In practice this means focus on the following aspects:

- Quality assurance system and quality policy
- Management leadership and personnel
- Premises and equipment
- Hygiene standards

- Documentation, labeling, document retention and traceability
- Production
 - Raw material specifications and acceptance
 - Utilities
 - Contamination prevention
 - Change control
 - Storage packaging, warehousing and transportation
- Quality control and specifications
- Control of work contracted out
- Complaint handling, product recall and incident management
- Regular internal and supplier audits

6. Quality assurance system and quality policy

The requirements given in this paragraph are general guidelines and may vary depending on the production process.

There is a quality policy directed towards the intended use, which is food contact. A quality assurance system involving the active participation of management and personnel shall exist.

6.1. Management leadership and personnel

Management responsibilities for good manufacturing practices implementation are assigned, defined and documented. The personnel supervising or performing the manufacture or control of food contact materials should have the education, training and/or experience to perform the assigned functions. The relevant personnel shall receive initial and ongoing training on good manufacturing practices related to the production of materials and articles intended for food contact. The training should be documented.

6.2. Premises and Equipment

Buildings, premises and equipment used in the manufacture or storage should be assessed in line with the specific production step and maintained to produce materials of a consistent quality suitable for food contact use.

Procedures are in place to avoid cross-contamination during production, storage, handling and transport.

6.3. Hygiene Standards

Appropriate hygiene standards are maintained for personnel, factories, warehouses and transportation.

A pest control program or the justification for lack of one should be documented.

6.4. Documentation, Labeling, Document Retention and Traceability

There is a documentation system in which product formula, operating procedures, operating windows and product release specifications and other critical information shall be documented.

There is traceability from incoming starting material to outgoing food contact material.

Major equipment, transfer lines, containers and tanks that are used to produce food contact materials are identified to indicate contents, batch designation, control status and other relevant information.

Samples from the end products, i.e. the material or article intended to come into direct contact with food, are retained for a specified time period depending on final usage.

Control records are maintained on items such as: raw materials, rejected materials, manufacturing conditions, production records, QC data, testing procedures and standards, test results, storage and distribution information.

The documentation shall be made available to the competent authorities upon request.

The above records ensure the compliance with article 7 of EU Regulation 2023/2006

7. Production

7.1. Raw material specifications and acceptance

Only approved suppliers are entitled to supply raw materials. Supplier acceptance is based on technical discussions with the suppliers of the raw materials to verify their quality standards. If needed, an audit will be performed at the supplier's premises.

Suppliers of raw materials have to be made aware and certify that their products are suitable to be used in production of materials or articles intended for food contact.

Raw materials are of a purity standard suitable for their intended use. Verification and acceptance of the raw material is based either on a supplier's certificate meeting the specifications or on incoming quality control.

Raw materials must be stored and handled in a manner which prevents their mix-up, contamination or deterioration.

Materials not meeting the acceptance criteria are properly identified and controlled to prevent misuse.

7.2. Utilities

Water that comes into contact with the food contact materials should be of suitable quality. The water supply must be tested regularly for conformance with requirements.

7.3. Contamination Prevention

There is an adequate contamination prevention procedure based on risk assessment.

There are effective transition procedures to avoid cross contamination when transitioning from non-food contact to food contact products.

There should be a physical separation or a validated control system to segregate raw materials and products from non-conforming materials.

Procedures are in place to avoid contamination through packing, loading and shipment operations.

7.4. Management of Change

Operation procedures and process operating windows have been established and documented. There is a procedure to control changes in operating practices or windows so that any changes affecting the composition or risk for contamination might be detected or flagged.

Changes in raw materials or raw materials suppliers are subject to change control.

7.5. Storage, Packaging, Warehousing and Transportation

Materials are clearly identified. Storage and transport conditions will avoid adulteration of the food contact materials.

8. Quality Control and Specifications

Documented specifications do exist for raw materials and finished products.

Raw material samples and products should be examined to determine their compliance with specifications and purity criteria. In the case of raw materials the examination can be done by the supplier and documented in a certificate of analysis. Suppliers are not required to provide customers with the undertaken evaluations.

Every food contact material code has one unique specification.

There is a change control procedure (management of change procedure) in place, which enforces a change in the food contact material code when the product formula and specifications are changed.

9. Control of work contracted out

Any manufacturing operation or operation linked thereto (e.g. warehousing) shall be subject to a written contract and good manufacturing standards comparable to the operation of the contracting body.

Work contracted out is subject to audits.

10. Complaint Handling, Product Recall and Incident Management

There is a system implemented for recording and investigating complaints including product recall if needed. The complaint investigation shall result in recommendations for corrective actions if needed.

There is a risk management procedure in place to handle contamination issues.

11. Regular Internal and Supplier Audits

There is a procedure in place to enforce regular internal audits or self-assessments to confirm / demonstrate compliance with good manufacturing practices.

There is a procedure in place to evaluate / validate the quality standards of a new raw material supplier before approval. This evaluation can be based on technical discussions and additionally on an audit at the supplier's premises if needed.