GUIDE OF GOOD MANUFACTURING PRACTICES FOR THE EU STEEL FOR PACKAGING INDUSTRY

Good Hygiene and Manufacturing Practices for Steel for Packaging
Intended to enter into contact with foodstuffs

TABLE OF CONTENTS *Page*

1. Scope

This guide of recommended good hygiene and manufacturing practices applies to the manufacture of steel for packaging intended to come into contact with foodstuffs.

Note : To get a complete view on how steel packaging, cans and closures intended to enter into contact with foodstuffs are consistently produced and controlled in accordance with the quality standards appropriate to their intended use, please refer to the French SNFBM "Guide to Good Hygiene and Manufacturing Practices for Metal Cans, Packaging and Closures intended to enter into contact with foodstuffs".[1]

2. Legal & Normative references

At EU level, the basic regulation applying to all food contact materials and articles is Regulation 1935/2004[2] establishing in its Article 3 that :

"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."

Three CEN standards specify the composition of steel for packaging intended to enter into contact with foodstuffs : the first one is specific to the base steel (i.e. "blackplate") used as a substrate to tinplate and ECCS; the other ones specify amongst others the composition of the metallic coatings applied to the base steel.

a) EN 10334 "Steel for packaging - Flat steel products intended for use in contact with foodstuffs, products and beverages for human and animal consumption - Non-coated steel (blackplate)"

b) EN 10333 "Steel for packaging - Flat steel products intended for use in contact with foodstuffs, products and beverages for human and animal consumption - Tin coated steel (tinplate)"

c) EN 10335 "Steel for packaging - Flat steel products intended for use in contact with foodstuffs, products or beverages for human and animal consumption - Non alloyed electrolytic chromium/chromium oxide coated steel"

[1] http://www.snfbm.fr/documentation.html#securite (« Guide de Bonnes Pratiques ») ; 22/6/2005. This national code is being used as a basis for drafting a future EU GMP for metal cans, packaging and closures intended to enter into contact with foodstuffs.
[2] OJEU L338, 13.11.2004

Metals & alloys – EU and national food contact regulation
Specific measures for metals, in the sense of Article 5 of Regulation 1935/2004, harmonising national regulations for that specific group of materials and articles are not yet available at EU level. Guidelines on Metals and Alloys used as Food Contact Materials have nevertheless been adopted by the Council of Europe[3]. Metals and alloys intended to enter into contact with foodstuffs are regulated by national laws.

National regulations on metals and alloys intended to enter into contact with foodstuffs : http://ec.europa.eu/food/food/chemicalsafety/foodcontact/sum_nat_legis_en.pdf

Coatings, plastics and lubricants[4] - EU and national food contact regulation

- Council of Europe Framework Resolution AP(2004)1 on coatings intended to come into contact with foodstuffs – national regulations also apply.
- EU Regulation 1895/2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food (e.g. applicable to lacquers used on ECCS and tinplate)
- EU Directive 2002/72 and amendments, Directive 82/711 and amendments, Directive 85/572 (applicable to the polymer used on polymer-coated steels).
- US FDA code of federal regulation (CFR) 21, § 178.3910 as surface lubricants used in the manufacture of metallic articles. National regulations also apply.

3. Definitions

A general definition of "good manufacturing practices" can be found in EC Directive 2003/94/EC Article 2.6[5] :

> *good manufacturing practice' means the part of the quality assurance which ensures that products are consistently produced and controlled in accordance with the quality standards appropriate to their intended use.*

ISO quality systems ensure that products are produced according to documented procedures and specifications whereas good manufacturing practices aim to ensure that products are consistently suitable for the intended use. Procedures set out in the ISO 9000 (on quality management systems) standards families, or other relevant guidelines such as the British Retail Consortium (BRC) Global Standard for Food Packaging and other Packaging Materials and ISO 22000 (both standards dealing with food safety management systems), can be used as a basis for building good manufacturing practices.

[3] Council of Europe, Technical Document, Guidelines on Metals and Alloys used as Food Contact Materials, 09.03.2001
[4] where applicable
[5] EC Directive 2003/94/EC laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational products for human use

4. Requirements

4.1. Design for compliance

Design for compliance is established through:

1. Regulatory compliance
2. Safety assessments, satisfying the requirements of Article 3 of EC Regulation 1935/2004.

The composition of steel as food contact material/component of food packaging must fulfil EN 10334 (blackplate) in combination with EN 10333 (tinplate) or EN 10335 (ECCS) in order to assure the integrity in terms of health and safety.

• Bare metal: fulfil requirements of EU Regulation 1935/2004 through compliance with EN 10334

And as applicable:
• Surface treatment: Safety Assessment – compliance with Article 3 of EC Regulation 1935/2004.

• Lubricated: compliance with US FDA Code of Federal Regulation (CFR) 21, § 178.3910 or Directive 2002/72

• Coated/Laminated: Plastic Directive 2002/72/EC and amendments.

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 organoleptic properties 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 judgement – if necessary supported by new safety assessments – needs to be made to confirm continued compliance with food contact Directives and Regulations.

5. Application of HACCP

Steel for packaging manufacturers have progressively and pro-actively applied the Codex Alimentarius HACCP (Hazard Analysis and Critical Control Point) principles for food hygiene to their own Good Manufacturing Practices for food contact materials.

The HACCP method allows identification of the potential hazard(s) specific to food

consumption, assessment of these hazards, and the determination of preventive measures to avoid their occurrence.

For each stage of a manufacturing process, the main potential hazards, means of prevention, critical control points (CCPs), means of inspection, and monitoring (pieces of evidence, documentation) which is ensured to control the identified CCPs. These hazards and CCPs serve as a basis for each company's own specific food safety policy.

6. Quality assurance system and quality policy

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 is in place.

6.1. Management leadership and personnel

- Management responsibilities and authorities for good manufacturing practices implementation are defined. Duties of personnel that relate to manufacturing or controlling food contact materials are provided in job descriptions or other suitable documents.

- Personnel should have adequate education or experience to perform those tasks.

- The organization provides training on good manufacturing practices related to the production of materials and articles intended for food contact for its personnel, and temporary and external staff to a level appropriate to the operations. Records of training are kept for all current and recent employees.

6.2. Premises and Equipment

- Buildings, premises and equipment used in the manufacture or storage are 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 is in place or the justification for lack of one is documented.

6.4. Documentation, Labelling, 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 is documented.

- There is traceability from incoming starting material to outgoing food contact material.[6]
- 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.
- Control records are maintained on items such as: raw materials, rejected materials, manufacturing conditions, production records, Quality Control data, testing procedures and standards, test results, storage and distribution information.

7. Production

7.1. Raw material specifications and acceptance

- Suppliers are approved on the basis of their ability to supply incoming materials and services in accordance with the specified requirements. Records are maintained.
- Suppliers are monitored. The results of the evaluation are recorded.
- Supplier acceptance is based on technical discussions with the suppliers of the raw materials to verify their quality standards. If needed, inspections or any other activities necessary to ensure that incoming materials meet specified requirements 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.

[6] Illustrative examples of how traceability of steel for packaging is ensured are contained in the "Industry guidelines on traceability of food contact materials and articles" – see EU Commission Joint Research Centre - Community Reference Laboratory on Food Contact Materials - website : http://crl-fcm.jrc.it/index.php?option=com_docman&task=cat_view&gid=41&Itemid=57

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 is 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. Change Control

- 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 are such that adulteration of the food contact materials is avoided.

8. Quality Control and Specifications

- Documented specifications do exist for raw materials and finished products.
- Raw material samples and products are 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.
- 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. Outsourcing

- In case of outsourced processes (e.g. manufacturing, warehousing), the organization ensures that comparable Good Manufacturing Practices are applied by the sub-contractor. There is a written contract.

- Outsourcing (sub-contracting) is audited, evaluated, approved and monitored by the organization. Records are maintained.

10. Complaint Handling, Product Recall and Incident Management

10.1. Complaint handling

- A procedure is established for dealing with complaints including product recalls, if needed.

- Subsequent actions are proportionate to the frequency and seriousness of complaints.

10.2. Incident management

- Procedures for dealing with incidents are established, and actions taken to eliminate them. Action is initiated to eliminate the causes of incidents to prevent a recurrence.

- Written guidance to its personnel on events that would constitute an incident is available.

- The nature of incidents and any subsequent actions taken is recorded. The effectiveness of the corrective action implemented is verified.

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

11. Regular Internal and Supplier Audits

- Internal audits or self assessments at planned intervals are conducted to assess that the good manufacturing practices are effectively implemented and maintained.

- Responsibilities for planning, conducting, and reporting results of audits/self-assessments and maintaining records are specified in a procedure.

- 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.

12. Annexes

12.1. Glossary

Blackplate

Low-carbon mild steel which has been subjected to cold reduction, is used mainly in the manufacture of tinplate and electrolytic chromium/chromium oxide coated steel and has a minimum iron content greater than 95% by mass (EN10334)

Contaminant

Agent responsible for contamination. It can be classed as chemical, biological (including microbiological) or physical in nature.

Contamination

Action of making impure or hazardous

ECCS

Electrolytic chromium/chromium oxide coated steel: Cold-rolled blackplate that is coated on both sides with a layer of chromium. The mass of the coating (total chromium) can reach 140 mg/m² per side (EN10335).

Hazard

Biological, chemical or physical contaminant in the product, or a condition of the product that may cause an adverse health effect or a nonconformity to the hygiene requirements for that product

Hygiene

Set of measures taken to ensure the wholesomeness, quality and safety of a product that might otherwise become hazardous or harmful

Incident

Event that may potentially compromise the wholesomeness, quality or safety of a material or product

Packaging

Any kind of product or material used by the packaging industry to wrap, pack, protect, handle or transport its own product

Product

Physical final output of any kind of production process that takes place in the (packaging) industry. This includes products that undergo further production steps to fulfil the specification defined by the filler/packer.

Risk

Function of the probability of the possible occurrence of a hazard and the severity of its outcome

Safety

Condition of a product being free from unacceptable risk or harm

Specification

Explicit or detailed description of a material, product or service including hygiene aspects

Tinplate

Cold-rolled blackplate coated on at least one side with a layer of tin. The mass of the coating can reach up to 15.1 g/m² (EN10333)

12.2. Simplified steel for packaging manufacturing flow chart