Good Manufacturing Practices for the production of coatings intended to come into contact with food ('Can Coatings')

CEPE[1] Code and Guidance Document[2]

2010 Update

[1] Conseil Européen de l'Industrie des Peintures, des Encres d'Imprimerie et des Couleurs d'Art

2 This Code and Guidelines are of a voluntary nature. Individual companies may decide to apply these either in full or partly, or not according to their own judgment.

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Preface

This guidance document has been produced by members of CEPE[3]. Its aim is to provide guidance on the good manufacturing practices and good hygiene practices in the manufacture of coatings, which are designed to come into contact with food (for humans or animals), when used on metal cans, ends, caps, closures, drums, or pre-formed containers where there is contact with foodstuffs.

This guidance document is intended to complement the Coatings Code of Practice for food contact coatings for light metal packaging. It describes how the coating industry can follow best practices as agreed by members of the CEPE. By following the guidance in this document and that in the Code of Practice, manufacturers have a methodology to ensure that all coatings for light metal packaging intended for direct food contact comply with Article 3 of the Framework Regulation (EC) No. 1935/2004.

This guidance document was developed to reflect the strong commitment of the European packaging coatings industry to comply with food contact and consumer safety requirements. The use of this guide is voluntary but strongly recommended.

The article 3 of the Framework Regulation (EC) No. 1935/2004 states that:

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

(a) endanger human health;

or

(b) bring about an unacceptable change in the composition of the food;

or

(c) bring about a deterioration in the organoleptic characteristics thereof.

GMP Regulation (EC) No. 2023/2006 outlines the requirements of GMP.

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Contents

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1. Introduction

Due Diligence

1.1 Regulations

The Framework Regulation (EC) No. 1935/2004 on materials and articles intended to come into contact with food requires that such materials and articles, including coatings, are manufactured in compliance with good manufacturing practice. The application of good manufacturing practice should ensure that such materials do not transfer their constituents to food in quantities which could;

(a) endanger human health; or
(b) bring about an unacceptable change in the composition of the food; or
(c) bring about a deterioration in the organoleptic characteristics thereof.

In 2006, the European Commission further emphasised the importance of having Good Manufacturing Practice regimes in place via Commission Regulation (EC) No. 2023/2006 on "good manufacturing practice for materials and articles intended to come into contact with food."
It is considered that the utilisation of appropriate manufacturing processes and hazard analysis and control systems, under the umbrella of a management system such as ISO 9001 should satisfy the requirements of Good Manufacturing Practice laid out in this Regulation. However, the adherence to an industry Good Manufacturing Practice recommendation provides an additional insurance against contamination of coatings for foodstuffs.

It should be noted that this guide should not be considered as a set of regulations in itself and does not excuse manufacturers of coatings or the articles onto which they are applied from their obligations in meeting all relevant regulations relating to their products.

1.2 Traceability

Due diligence also requires full traceability along the supply chain. Article 17 of Framework Regulation (EC) No. 1935/2004 calls for "the traceability of materials and articles (intended for use in contact with food) shall be ensured at all stages in order to facilitate control, the recall of defective products, consumer information and the attribution of responsibility."

The packaging coatings industry supports this principle and all coatings designed to come into contact with food should be traceable by discrete product, individual batch/lot, back through to the individual raw materials used in manufacture, the raw materials' batch/lot and supplier.

2. Objective

Good Manufacturing Practices (G.M.P.) are embodied in a Total Quality Management System as described in the ISO 9001 standard.

Procedures for formulation, production, control and warehousing are defined in order to warrant that surface coatings intended to come into contact with food:

- comply with existing regulations and/or generally accepted requirements for packaging and articles intended to come into contact with food.
- are fit for the purpose intended.
- meet agreed customers' and end use specifications.

3. Scope

These Good Manufacturing Practices apply to the manufacture of organic coatings which are designed to come into contact with foodstuffs, for humans or animals, when used on the following types of containers or components thereof:

- lightweight metal cans and ends (including 2-piece, 3-piece, monobloc aerosols, composite containers, etc.)
- caps or closures for jars or bottles

The range of coatings concerned are applied onto metal substrates, at relevant stages of the substrate's conversion into the final container.

4. Definitions

Good Manufacturing Practice (G.M.P.) is a system for ensuring that products are consistently produced and controlled according to quality standards. It is designed to minimise the risks involved in any production of coatings designed for food contact that cannot be eliminated through testing the final product. The main risks include:

- unexpected contamination of products, causing damage to health,
- incorrect labels on containers, which could mean that customers could receive the wrong product.

G.M.P. covers all aspects of production, from the starting materials, premises and equipment to the training and personal hygiene of staff.

5. Hazards to be Considered

Potential contaminants of coatings intended to come into food contact include –

- chemicals raw materials that are not covered under the requirements of EU "Framework" Regulation No. 1935/2004, European Directive 2002/72 EEC (or subsequent amendments) or the USA FDA regulation 175.300.
- chemical products not associated with the formulae of coatings designed to come into contact with food – e.g. lubricating oils, greases, sprays, etc.
- biological or microbiological entities or products - e.g. spoiling micro-organisms present on birds or their droppings, feathers, insects, hair, algae, etc.
- physical articles - intact or damaged – e.g. pens, pins, knives, blades, broken glass, tooling swarf, etc

6. Controls

6.1 Manuals

Detailed written procedures exist for each process step, from the development of coatings designed for food contact, to receipt of the order for the products, through manufacture to delivery of the coatings that could affect the quality of the finished product.

There are systems to provide documented proof that correct procedures are consistently followed at each step in the manufacturing process – every time a product is made.

6.2 HACCP System

A Hazard Analysis and Critical Control Process (HACCP) system exists for the range of food contact coatings produced by a manufacturer. The HACCP system encompasses all stages of the process, from raw materials and their storage and handling, coatings manufacture, filtration, filling into containers, storage and delivery, including all plant engineering and maintenance aspects.

The HACCP system need not be third-party approved but shall be part of, or linked to, the plant quality management system.

It is recommended that individual Critical Control Points (CCP's) are identified by local risk assessment of each process. A Critical Control Point is a step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level. A CCP is a key step at which control must be applied to prevent or minimise issues relating to prevention of contamination of food contact coatings.

6.3 Production Instruction Document

Document(s) detailing the product's ingredients and manufacturing instruction (e.g. batch sheet) are produced for each batch of coating manufactured. The documents may be in the form of paper or electronic format and clearly state that the product is for food contact use. It details the actions required by the production staff for manufacture and the materials, quantities and equipment to be used. Any critical feature of the process is highlighted by requiring a specific action by the operator, which is recorded as being completed. Examples of such documents appear as Appendix 1 to the G.M.P.

6.4 Product Test Specification

Product Test Specifications exist for each coating manufactured. They list the tests, which are required during manufacture and on completion to ensure the batch meets the coating specification and is fit for intended use.

The specification contains, where appropriate, the tolerances for each test.

The relevant test includes a reference to a specific method contained in a manual of test methods detailing the procedure to be used.

6.5 Pest Control

The plant shall employ pest control measures throughout the site to eliminate the presence in any area of the site of any rodents, birds, crawling insects, etc.

7. Quality and Process Problems

In the event of a non-compliance at any stage of the process or a complaint, a procedure exists to find the cause, rectify the problem and if necessary make the appropriate improvement(s) to the procedures or other controls to prevent a repetition. A person is appointed who is independent of the production and quality control functions to accept responsibility for ensuring that any non compliance issue is dealt with and that corrective actions are completed.

8. Personnel and Training

8.1 Commitment

The entire workforce, involving all levels of management is committed to the objectives of G.M.P.

8.2 Training

Training programmes and facilities are established to ensure that all personnel are fully aware of their functions and responsibilities and are competent to carry them out.

9. Raw Material Controls

9.1 Objective

G.M.P. requires complete co-operation with the suppliers of raw materials and knowledge of the needs of the customer. Raw materials are carefully selected to ensure that the components of the food contact coatings comply with the requirements of legislation are suitable for the quality of the product and are within agreed specifications.

9.2 Suitability

Raw materials are selected in line with the requirements of food contact legislation so that, when the coating is correctly applied and cured, the coating should not:

- endanger human health
- cause deterioration in the organoleptic nature of the packed foodstuff
- bring about an unacceptable change in the composition or quality of the packed foodstuff.

Documentary evidence exists to confirm the fitness for use in contact with food, for each film-forming raw material used in the coatings concerned, in compliance with European Directive 2002/72 EEC (or subsequent amendments) or the USA FDA regulation 175.300.

9.3 Identification

A name, reference number and batch or delivery number identify each raw material, so it can be traced, as required by Regulation 1935/2004 of the European Parliament.

9.4 Specification

Each raw material has a specification, agreed between the supplier and the coatings manufacturer. The specification includes physical and chemical properties to maintain agreed coating manufacturing quality and end-use technical requirements. It should ensure consistency, fitness for use and conformity with appropriate food contact directives, legislation and regulations when used for the manufacture of food contact coatings.

9.5 Conformity

Raw materials are only taken from approved suppliers and are delivered in compliance with specification, or variance agreed by documented concession.

Confidence in raw material suppliers is established by audit and continual assessment.

Contamination prevention measures are in evidence where raw materials are delivered in bulk from the supplier.

Where relevant, raw materials may be tested and approved for use in final products using test methods agreed between the supplier and the coating manufacturer. Where possible well known, internationally and industry accepted methods of test and chemical analysis should be used. Where appropriate they should be those which comply with any E.U. directives or national legislation. Where possible reproducibility by both parties should be established.

Where appropriate, raw materials are supported by a certificate of conformity from the raw material supplier, agreed relating to the specification.

9.6 Traceability

Traceability of a batch of raw material is achieved by using the name/reference number and a delivery/batch number throughout the system.

If batch referencing is not possible an alternative system is put in place.

9.7 Storage

Raw materials are stored under conditions to prevent contamination or deterioration. Rejected materials are clearly marked as such.

9.8 Usage

Raw material stocks are rotated and used on a first-in first-out (FIFO) basis.

10 Coatings for Food Contact

10.1 Formulation

The following parameters are considered when formulating food packaging coating:

- type of substrate and material combinations
- type of foodstuffs to be packed
- type of lacquering processes and lacquering equipment
- package-forming and filling processes
- end-user specifications
- compliance to health, safety and consumer protection regulations
- compliance with environmental policies for lacquering, manufacturing processes

and end-use.

Food packaging coatings are formulated such that, when appropriately applied and cured, the coatings will:

- have the necessary adhesion to the substrate and resistance to physical and chemical stress.
- are suitable for the method of application and for subsequent converting processes.
- meet product resistance specifications such as ISO standards or other agreed end use specifications.
- will cause no deterioration of the organoleptic nature of the packed food stuff.
- be compliant with existing legal provisions.

10.2 Identification

Each coating intended for food contact is identified by a descriptive title or trade name and a unique reference number. Each batch also has a unique distinctive number.

10.3 Data sheets

Each product shall have a corresponding Material Safety Data Sheet (MSDS) and Technical Data Sheet (TDS). The TDS will detail the product's specification (e.g. solids content, viscosity), relevant chemical and physical data, recommended end uses, application method, film weight and curing conditions.

A separate statement may also be provided that the coating conforms to appropriate food contact directives, legislation or regulations.

10.4 Test Methods

Test methods are agreed by the coating manufacturer with a user customer, when the tests should be reproducible by both parties where possible.

In all cases, where possible, well known internationally and industry accepted methods should be used. Where appropriate they should be those developed by E.U. sponsored organisations such as C.E.N. or national standards.

When these methods do not exist the tests used should be fully documented and meet realistic acceptable standards of reproducibility.

When coatings are sold to various end users, comprehensive details of test methods should be made available to the end user on request.

10.5 Conformity

Upon specific customer request, each delivery of coating is supported by a certificate of analysis/conformity confirming that it meets the agreed specification.

N.B. These batch/delivery certificates serve no functional purpose and provide no absolute guarantee that a batch or delivery will perform without any unforeseen quality issues; neither are they a requirement of ISO9001 and as such the provision of these certificates is discouraged.

10.6 Delivery

Each individual container of coating should be delivered to the customer in accordance with pre-agreed details for each delivery order, where the following are specified:

- Material(s) Required
- Quantities Required
- Packaging Details
- Delivery Date (and Time where relevant)
- Delivery Point
- Price

11. **Production**

11.1 Objective

To convert raw materials safely and efficiently into the finished product(s) which meet the declared specification(s) and ensure that the labelling and packaging meets the requirements of the customer.

11.2 Formula and Control

The coating's formula is designed so that the product meets the required quality standards without any undue adjustments.

The formula as made into final product matches precisely the original formula that was tested and approved by the formulating chemist, the customer and/or the filler.

11.3 Manufacturing Instruction Document

Manufacturing instruction document is issued with each batch giving details of the raw materials with the quantities to be used. It highlights the critical parts of the process and provides the facility for the requisite actions to be recorded and certified by the operator. It is acknowledged that the variety of coatings manufactured coupled with the many different processes used, prohibits the production of manufacturing guidelines. A coating can be

manufactured successfully in a number of ways using different equipment. Prevailing conditions and batch size will require significant modifications to the process.

An appendix to this document models instruction documents with comments. Appendix 1 refers to the manufacture of a lacquer intended for application to a metallic substrate to be used to make a component of a food container, such as a can body, can end, or a closure for a glass or plastic bottle or jar.

The simplest of operations, the blending of solvents, resin solutions and an additive has been selected for the sake of brevity.

The coating would usually be cured by some heating process. It would be required to withstand some mechanical forming operation.

The appendix is intended as examples, they do not cover every possible feature of the processes, but do illustrate the "philosophy" of a G.M.P. manufacturing instruction document.

11.4 Equipment

The equipment used is suitable to manufacture the products required. It is kept in good repair with a documented inspection and maintenance schedule appropriate to the particular piece of equipment.

All measuring, metering or weighing equipment that are used as part of the production process is subject to calibration checks at defined intervals.

11.5 Cleanliness

The use of plant dedicated to the manufacture of food contact coatings is most desirable but not essential. Where possible plant should be used for the production of a single product or family of products only.

Written plant cleaning and inspection procedures exist to ensure removal of any undesired material from all equipment prior to the manufacture of the coating. Filtration is an integral part of the process to remove unwanted solid particles at the end of the process.

11.6 Health, Safety and the Environment

The working conditions and manufacturing equipment are designed and operated to conform to the relevant requirements of National and European Occupational Health and Safety and Environmental Protection Legislation.

12. **Packaging**

12.1 Specification

The packaging is selected, where possible, in agreement with the customer, to meet the customers use requirements and to protect the food packaging coating during shipment and storage. It conforms to appropriate National, European and UN requirements for the nature of the product packed and the means of transport.

12.2 Cleanliness

Containers are individually inspected for cleanliness prior to fill and are sealed immediately after filling.

Returned multi-use containers are cleaned to remove residual product and any contamination from foreign materials and are inspected before re-use.

12.3 Accurate Filling

Filling controls are accurate within legal measuring limits. All weighing equipment is examined for accuracy, re-calibrated if necessary and frequently inspected.

12.4 Labelling

Each container carries labels showing, where appropriate: -

- Identification of the producer
- Reference number (and trade name where appropriate)
- Batch number
- Expiry Date
- Safety Labelling in accordance with national and international directives, legislation and regulations.
- Gross Weight and Net Weight

13. **Quality Control**

13.1 Objective

To carry out laboratory tests on coatings in production and finished products to ensure that coatings supplied to the customer are fit for application and end use and conform to agreed customer specifications.

13.2 In-process Quality Control

Testing of samples at selected stages of the process is carried out to establish whether the product is meeting the required quality standard. A procedure is set up for the production personnel to adjust the process to meet the specified limits when necessary.

Testing is not limited to the laboratory or laboratory personnel. It may be carried out by any trained authorised person at a convenient location.

13.3 Finished Product Testing

The finished product is tested to meet the product specification and the test methods contained therein. Due regard is paid to all directive, legislative and regulative requirements, relevant to the particular product and its end use.

A document is completed detailing tests carried out and the results, stating whether it meets the required quality standards or not.

13.4 Test Equipment

All test equipment is tested and/or calibrated according to a schedule to ensure that the test results are accurate. The test information is recorded and appropriate action taken to repair or replace equipment if it fails the calibration test, is damaged or obviously malfunctions.

14. **Warehousing**

14.1 Conditions

Raw materials and finished coatings are stored in conditions to prevent any deterioration of the material.

14.2 Raw Materials

Raw materials are stored in appropriate containers in a manner to prevent contamination and spillage. They are clearly marked with the agreed product description and or code, which include a reference to the delivery date.

Areas are allocated to approved materials and when tested in-house they are marked as such.

Unapproved or rejected materials are quarantined. A procedure must exist to prevent their use in production. They are (preferably) kept in a separate designated area.

Materials are used on a first-in-first out (FIFO) basis.

14.3 Finished Products

Approved materials are marked as such and kept in a dedicated area. They are sent to the customer on a FIFO basis.

A procedure exists to re-test stock if it is approaching its expiry date or may have drifted out of specification, before despatch to the customer.

Rejected stock is clearly marked as such and isolated to avoid accidental use.

14.4 Delivery

All products are delivered in clean and clearly labelled suitable containers.

APPENDIX 1

Manufacture of Lacquer 12345
Batch Size - 1000 Kg
Equipment to be used - Vessel No. 1

Ingredients

Solvent C	(K litres)	A Kg	
Solvent D	(L Litres)	B Kg	
Resin Solution A			X Kg
Resin Solution B			Y Kg
Additive F		M Kg	
Solvent C		Hold R Kg	
Solvent D		Hold S Kg	

Preparation

Equipment checks specified in Detail

	Operator
Vessel cleanliness	_ sign
Specific mechanical checks	_ sign
Pollution control equipment in place	_ sign
Personal safety equipment used	_ sign
Check Raw Materials	
1. Solvent C piped K litres	
2. Solvent D piped L litres	_ sign
3. Resin Solution A (J drums) Batch 89	_ sign
4. Resin Solution B (H drums) Batch 69	_ sign
5. Additive F 10 kg Batch 67	_ sign
	_ sign

	Operator
Loading Procedure	
Load ingredients in order. Mixer speed G. rpm	_ sign
If order of addition and/or speed is crucial this should be specified, recorded and signed and times recorded and signed.	
Mixing Procedure	
Mixer speed 1 on time off time Mixer speed 2 on time off time	_ sign _ sign
If temperature control is important limits should be set.	
Temperature recorded and signed at specified intervals.	
Instructions detailing what to do if limits are reached.	
At end of mixing record time Reduce speed to minimum Sample to laboratory	_ sign _ sign _ sign
Laboratory Process Check	
Limits specified in Product Test Specification	
Viscosity Record Signed by tester	
Viscosity is likely to be high to allow addition of part or all of Solvent C - R Kg and Solvent D - S Kg.	
Laboratory instructs operator in writing on the instruction document quantities of solvents to add.	
This is added by method detailed in the instructions	_ sign
Mechanical Properties	Operator
For example:-	

1. Flexibility test for can end lacquers closure coatings or to measure resistance to fracture due to denting of a can body.

2. Drawing test for closure coatings or drawn can coatings.

Resistance Properties

For example:-

Pasteurisation for beer can lacquers and some closure coatings.
High process for processed food can coatings.
Sulphur staining for high protein processed food can coatings.

When the batch of coating is shown to comply with the specification the laboratory authorises, in writing on the instruction document, for it to be filtered and filled into containers.

Preparation of Specified Filter

e.g.

Cleanliness	_ sign
Other details	_ sign
Personal safety equipment	_ sign
Connect to lacquer tank	_ sign
Start to recycle - time - record	_ sign
Recycle x minutes	_ sign
Sample to laboratory	_ sign

Laboratory approves cleanliness in writing on instruction document.

Filling

Start filling into containers specified
Check containers for cleanliness
Check filter at specified intervals - operator records and signs.

_ sign

Limits are set for operation of the filter, for example pressure.

Instructions given if limits are exceeded.

Samples are tested at given intervals by operator and/or laboratory. Results and times are recorded and signed.

A sample is taken during the filling process and retained in controlled conditions for a minimum of 1 year.

After the coating has been loaded into the containers the yield is calculated and recorded.

If all testing and control criteria are within the limits specified, the batch is approved.

The batch is then moved to warehouse control for shipment to the customer.

In the event of a batch failing to meet any of the quality standards the batch is not approved, it is marked with rejected labels and is referred to the relevant manager, who initiates an investigation and takes appropriate action.

The batch is moved to the designated area in the warehouse for rejected stock.

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