

# HARRPA Good Manufacturing Practices (GMP) for Food Contact Substances

**HARRPA**

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*The Hydrocarbon Resins, Rosin Resins and Pine Chemicals Producers Association (HARRPA) has been formed more than 25 years ago as a non-profit making international Sector Group. It operates within the European Chemical Industry Council (Cefic) structure.*

Pour de plus amples informations veuillez consulter notre site internet [www.harrpa.eu](http://www.harrpa.eu) ou contacter Mr Joël Wilmot, Sector Group Manager HARRPA, Cefic : +32 2.676.72.88 or jwi@cefic.be

*HARRPA regroup 16 member companies in Europe for a total yearly production of more than 1 million tons and a total turnover around 1.5 billion euros. The members have about 32 production sites in Europe and employ more than 3000 people.*

**A sector group of Cefic** 

European Chemical Industry Council - Cefic aisbl

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# 1. INTRODUCTION

HARRPA members manufacture resins, which are further formulated by downstream users. Among various applications, our resins find their way up in food contact materials (= FCM). The main applications for FCM containing resins are: adhesives, coatings, and inks.

In the European Union (=EU), the main legislation is Regulation (EC) 2023-2006. Good manufacturing process (=GMP) regulatory compliance is believed to directly apply to raw materials such as the resins supplied by HARRPA members when used in FCM applications. However provisions found in Regulation (EC) 2023-2006 appears very generic.

In the United States of America (USA), food contact material is regulated through parts 174, 175, 176, 177 and 178 of 21 CFR. Section 174.5 provides the general provisions applicable to indirect food additives but this section is very generic. However current GMP as defined in parts 117 are applicable for food and dietary supplements operations.

In both the US and the EU, provisions for GMP are not very detailed. General principles must be followed to assure product quality in its food contact applications. As far as we know, there is no existing standards or official guidance for FCM. As a result, many professional associations have prepared their own guidance documents. HARRPA has decided to prepare its own position and provides here a guidance adapted for the manufacturing of our resins as raw materials as used in food contact materials.

## Scope

GMP is for all materials and articles, which are intended to be brought into contact with food or where migration into the food is possibly expected under the conditions of use.

The present guideline intends to cover both direct and indirect food contact substances with no distinction whatsoever and provides what HARRPA considers as an acceptable level of requirements for food contact materials.

## This guidance is dedicated:

- to our members: to assist in selecting the appropriate guidelines as relevant for specific application.
- to our customers and downstream users: to show how HARRPA members apply GMP for their resins.

## Engagement

This does not imply that the present guidance must be strictly followed by HARRPA members as the application defines what guidelines are recommended to adhere to. At least HARRPA members have recognized the need of such guidance and are aware of GMP requirements for FCM.

### Size of the business

Regulation (EC) 2023-2006 clearly states that the quality assurance system should be proportionate to the size of the business to avoid undue burdens for small businesses.

### Definitions

- **Resins:**  
The raw materials are derived from petrochemicals and natural materials from trees. After processing, the raw materials are used to produce resins. More details by product family can be found directly on the HARRPA website: [www.harrpa.eu](http://www.harrpa.eu)
- **Food Additive:**  
FDA - A food additive is defined in Section 201(s) of the Food Drug & Cosmetic Act as any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristic of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use); if such substance is not GRAS or sanctioned prior to 1958 or otherwise excluded from the definition of food additives.
- **Direct Food Additive – US based definition:**  
Ingredient added into food for technical effect - intended use results in it becoming component of food. Examples: antioxidant, food colorant, sweetener, thickener, etc.
- **Indirect Food Additive- US based definition:**  
Additive not added to food but used in for example food packaging. It may migrate into food but that is not the intent.  
Under FDA defined as food additives that come into contact with food as part of packaging, holding, or processing, but are not intended to be added directly to, become a component, or have a technical effect in or on the food. Also known as Food Contact Substance.
- **Food Contact Material (FCM):**  
Any material that is expected to come into contact with food.
- **Food Contact Substance (FCS):**  
Under FDA defined as any substance that is intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use of the substance is not intended to have any technical effect in such food. Also known as Indirect Food Additive.
- **Direct Food Contact:**  
Substance or material that comes into direct contact with food upon use. An example is adhesives used in labels that are directly applied onto food such as apples or meat (i.e. FDA 175.125).

- **Indirect Food Contact:**

Adhesives used in labels which are put onto packaged materials or adhesives which are used to seal food packages, i.e. hotmelts in cereal boxes, etc. In the first case adhesives components may migrate through the packaging into the food. The packaging is functioning as a barrier. In the second case, the seam area on the edge may be exposed to food. There is limited contact with food in the edge area (FDA 175.105).

**Acronyms**

QMS : QUALITY MANAGEMENT SYSTEM

GMP : GOOD MANUFACTURING PRACTICES

FCS : FOOD CONTACT SUBSTANCES

FCM : FOOD CONTACT MATERIALS

QA : QUALITY ASSURANCE

QC : QUALITY CONTROL

FDA : FOOD AND DRUG ADMINISTRATION

## 2. QUALITY MANAGEMENT SYSTEM (QMS)

The design of a “GMP” program can build upon existing internal quality program.

The present guideline only describes (or details) additional practises. The main difference lies in the control of the product purity/quality, which is usually not needed for general industrial applications since they focus mainly on the technical performance. The hazard analysis determines if and which specific processes and controls are needed for achieving food contact GMP. Another very important aspect relies on the delivery of the right product to the customer by avoiding any shipping or labelling mistakes.

### 2.1 Scope of Quality Management Systems

#### 2.1.1. Non conformity management

In the event of non-conformity at any stage of the process or a confirmed customer complaint, a procedure exists to take corrective and preventative actions to find the cause, rectify the problem, and if necessary make the appropriate improvement(s) to the manuals or other controls to prevent a repetition. A person is appointed to accept responsibility for ensuring that any non-conformity issue is dealt with, and corrective action completed.

#### 2.1.2. GMP inspection

Implementation and achievement of GMP is monitored by performing internal inspections on a regular basis, for instance as part of the normal quality management audits. Corrective actions are identified to correct any failure to achieve GMP. These are implemented without delay.

This guideline can be easily transformed into an inspection-checklist to be prepared by each specific company.

### 2.1.3. Traceability

The downstream traceability of materials is required. Finished products are identifiable by an appropriate system such as labelling, or relevant documentation and information. Traceability of products is achieved by the delivery / batch reference numbers throughout the system. If batch referencing is not possible, an alternative system has to be put in place in order to achieve as much traceability as possible without becoming an excessive burden for the business.

### 2.1.4. Quality control (QC)

QC should be in place (testing on resins: Laboratory tests on the resin in-process and on the resin finished products) and carried out to ensure that resins supplied to the customer are fit for application and end use and conform to agreed customer specifications.

## 2.2 Documentation

As part of a QC system all relevant documentation shall be archived and maintained to allow for inspection and corrective actions.

### 2.2.1 Manuals

Detailed operational manuals cover receipt of orders, formulation, manufacture, quality control testing plan and methods, and product delivery to agreed standards.

### 2.2.2 Production Instruction Documents

An instruction document (e.g. batch card) is issued for each batch of resins manufactured. This details the materials, quantities and equipment to be used and highlights any specific precautions to be followed.

### 2.2.3 Product test specification

Product Test Specifications exist for each resin manufactured. They list the tests (and methods), which are required during manufacture and on completion to ensure the batch meets the resin technical specifications and contain, where appropriate, the tolerances for each test. The specifications for resins used in food packaging applications might be more specific taking into account impurities and possible contaminants.

## 3. COMPOSITION & SAFETY ASSESSMENT

### 3.1 Composition

Composition of the raw materials of the resins designed and/or promoted for food contact applications should be properly determined, documented and assessed.

Specifications are set up at the development stage in order to ensure that the resins produced will consistently meet the composition requirements for food contact materials.

### 3.2 Safety assessment

The establishment of GMP requires an analysis of the potential hazard(s) in the entire process.

#### *Hazard to be considered:*

All potential sources of contamination of the resins should be considered in hazard assessment, including:

- chemicals/raw materials that are not covered under the requirements of EU “Framework” Regulation No. 1935/2004, Commission Regulation (EU) No 10/2011 (or subsequent amendments) or the USA FDA regulation 175.300 or 175.105, 175.125....
- chemicals/raw materials that are covered under the above-mentioned regulations but which may be present in a not specified concentration and may therefore exceed the limits set forth in the regulations (e.g. maximum quantities, specific migration limits).
- biological or microbiological entities or products - e.g. algae in waterborne emulsions products
- physical articles - intact or damaged – e.g. pens, pins, knives, blades, broken glass, tooling swarf, etc.
- NIAS (not intentionally added substance)

A safety assessment is carried out for all resins components, not limited to monomers and additives, but including all components of the resin.

## 4. Layout of premises and workspaces

### 4.1 General requirements

Buildings shall be designed, constructed and maintained in a manner that is appropriate for the processing, packing and warehousing operations to be carried out.

Premises and workspace layouts should be designed, constructed and maintained to assure good hygiene and manufacturing practices are implemented. The movement patterns of materials, products and people, and the layout of equipment, should be designed, installed and maintained to protect against potential contamination of the product.

## 4.2 Internal design, layout and traffic patterns

The building should be of sufficient size and design, with a logical flow of materials, products and personnel, and physical segregation of raw materials from processed product areas to assure finished product is not contaminated.

NOTE: Examples of segregation may include walls, barriers, partitions, or sufficient distance to minimize risk. Where distance alone is utilised, sections of each building should be marked off (tape, paint or other suitable marking) and designated for raw materials, rework, finished product, and packaging materials processing and storage

Openings intended for transfer of materials shall be designed and secured to minimize entry of unauthorized personnel, foreign matter and pests.

## 4.3 Location of equipment

Equipment should be designed and located so as to facilitate cleaning and monitoring.

It should be located to permit access for operation, cleaning and maintenance.

## 4.4 Storage of food contact materials, raw materials and packaging materials

Facilities used to store raw materials, packaging, in-process and finished products must provide protection from dust, dirt, water, pests, waste and other sources of contamination.

Storage areas should be clean, dry and well ventilated. Temperature and humidity should be monitored and controlled where specified (whenever temperature and/or humidity control is necessary to assure product safety).

Storage areas should be designed and maintained to assure segregation of raw materials, work in progress and finished products.

Materials and products should be stored off the floor with adequate space between the material and the floor or walls to allow inspection, cleaning and pest control activities to be carried out.

The storage area should be designed to allow maintenance and cleaning, prevent contamination and minimize deterioration.

Cleaning materials, chemicals and other hazardous substances must be secured in a separate storage area to minimize the risk for product contamination.

## 5. Utilities — air, water, energy

### 5.1 General requirements

General Process guidelines are designed based on specific process requirements: e.g. food contact.

The provision and distribution routes for utilities to and around processing - Storage areas must be designed to minimize the risk of product contamination.

### 5.2 Boiler chemicals

Boiler chemicals, if used, shall be stored in a separate, secure area when not in immediate use.

Boilers chemicals should be identified and meet national regulatory requirements.

### 5.3 Air quality and ventilation

Ventilation systems if needed shall be designed and constructed such that air does not flow from contaminated or raw areas to clean areas.

Exterior air intake ports if used shall be constructed and maintained to prevent contamination, e.g. Use of filters.

Protocols for air quality monitoring and control shall be established in needed areas.

### 5.4 Compressed air and other gases

Compressed air, carbon dioxide, nitrogen and other gas systems used in manufacturing and/or filling shall be constructed and maintained to prevent contamination.

Gases intended for direct or incidental product contact shall be from a source approved to meet food contact requirements.

### 5.5 Lighting

Resins shall be prevented from any contamination (i.e. by light fixtures in case of breakage).



## 6. Equipment suitability, cleaning and maintenance

### 6.1. General requirements

Equipment used for FCM's shall be designed and constructed to facilitate cleaning, and maintenance.

Contact surfaces shall not affect, or be affected by, the intended product or cleaning system.

### 6.2. Product contact surfaces

Product contact surfaces shall be constructed from materials designed for food-contact resins use: surfaces should be inert and should not transmit any contaminants to the resins. They shall be impermeable and rust or corrosion free.

### 6.3. Cleaning plant, utensils and equipment

Cleaning programs shall be documented to ensure that equipment are cleaned at defined frequencies.

### 6.4. Preventive and corrective maintenance

A preventive maintenance programme shall be in place.

NOTE Examples of such devices include screens and filters (including air filters), magnets, metal detectors and X-ray detectors.

Corrective maintenance shall be carried out in such a way that production on adjoining lines or equipment is not at risk of contamination.

Maintenance requests which impact product safety shall be given priority.

Temporary fixes shall not put product safety at risk. A request for replacement by a permanent repair shall be included in the maintenance schedule.

Lubricants and heat transfer fluids shall be assessed for their intended use.

The procedure for releasing maintained equipment back to production shall include clean up and pre-use inspection.

Maintenance personnel shall be trained in the product hazards associated with their activities.

## 7. Management and quality of purchased materials

To achieve a satisfactory management of purchased raw materials and an acceptable level of quality, it is required to have co-operations with suppliers of purchased materials and knowledge of the needs of the customer. Although standard industrial raw materials are generally used, they shall be carefully selected to ensure that each ingredient of the food contact resin is of a suitable quality (purity) for the product and is within agreed specifications. The conformance of incoming materials to specified purchase requirements shall be verified.

Raw materials means:

- Raw materials used for the manufacture of the resins
- Processing aids
- Packaging and utilities

### 7.1. Selection and approval of purchased materials

Raw materials used during production process should be selected and approved. They shall be of suitable quality and within agreed specification in order to guarantee the suitability of the resins for the food contact applications.

A procedure describing the selection and the approval of new purchased materials is recommended:

- A risk assessment step is performed according to the needs of each resins producer (e.g. designation of chemical component(s), the supplier specification of new purchased material, its safety data sheet, any certificates about contaminants or compliance, and any potential food contact certificate (for plastic bags used in packaging or lubricants used in production for example)).
- For the approval phase, the procedure should define the different steps enabling to approve all types of purchased materials, which could have an impact on the use of resins in food contact application.
- When feasible the approval of new raw materials should end with the drafting of specific raw materials specification that should be signed by both suppliers and customers. This will serve as the basis for the elaboration of the certificate of analysis for this new purchased component.

Note:

To approve a new raw or purchased materials, it is needed to ensure that materials purity is suitable for its use in the manufacture of food contact resins. Special attention shall be paid to the substances of concern such as the Carcinogenic, Mutagenic, Toxic to Reproduction and Neurotoxic substances (CMRN) which may have very low tolerable daily intakes.

Specifications should be established, reviewed and re-validated on a regular basis, as deemed appropriate.

## 7.2. Control of incoming materials

A procedure describing the reception and the approval of batches of purchased materials delivered by the supplier, should be implemented. In order to verify the correct delivery of a purchased material, the procedure should specify the following items:

- identification (name and batch/lot number),
- documents provided by the supplier,
- storage,
- sampling,
- testing,
- and approval or rejection of materials.

For all raw materials (bulk and conditioning) intended to be used in food contact resins, an inspection shall be done at their delivery. The suppliers Certificate of Analysis, if available, shall be analysed to verify the conformity towards the agreed raw materials specifications. A visual inspection is recommended and ideally a sample shall be taken in order to be tested. Based on the inspection and the analysis of CoA (or results of sample evaluation), the raw or purchased materials shall be cleared for reception or rejected.

Materials which do not conform to specification defined with supplier(s) are prevented from unintended use.

Note: The storage infrastructure for bulk materials must be identified, capped and locked. Their discharge into these systems must be performed after their inspection and an approval of their conformity with their specifications.

## 7.3. 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.

A traceability system should be mandatory and is a result of legislation. The internal auditor (or system leader) should check the batch and/or lot identification in records maintained throughout the process from material receipt to end product dispatch. There should be a time mandated for this traceability process. Also the organization needs to define a retention period for traceability records which is related to system assessment and considers the implications for disposition of potentially unsafe products and product withdrawal.

## 7.4. MANAGEMENT OF SUPPLIERS

There shall be a defined process for the selection, approval and monitoring of suppliers.

The level of requirements and involvement should be adapted to the suppliers.

The process used shall be justified by hazard assessment, including the potential risk to the final product, and could include:

- a) assessment of the supplier's ability to meet quality and food contact safety expectations, requirements and specifications;
- b) description of how suppliers are assessed;

## 8. Measures for prevention of cross-contamination

### 8.1. General requirements

Programs should be designed and implemented to prevent, detect, and control product contamination. Measures to prevent physical, chemical, and microbiological contamination shall be included in the programs.

### 8.2. Microbiological cross-contamination

It is important to highlight that resins have generally been heated to temperatures greater than 100°C during manufacture. Dry resins generally have an  $a_w < 0.8$ . Therefore microbiological development is very unlikely to occur therefore controls are generally not necessary.

Despite all these precautions, microbiological cross contamination may occur during or after the manufacture of the resins. However, resins are not considered as an appropriate media for microorganism's growth. Therefore microbiological testing is not recommended directly on these resins.

Areas where the potential for microbiological contamination exists (airborne or from traffic patterns) shall be identified and a segregation or zoning plan implemented. A risk assessment should be carried out to identify any potential contamination sources, after the resins have been cooled down the susceptibility of the product to those potential contaminants and any control measures needed to address them.

### 8.3. Physical contamination

Based on a hazard assessment, measures shall be put in place to prevent, control or detect potential contamination.

### 8.4. Chemical contamination

Cross-contamination between successive batches of food contact resins of different composition should be avoided or, when not technically/ economically possible, it shall be reduced to a minimum, assessed to pose no risk to human health and kept under control.

Examples of means to avoid cross-contamination:

- Dedicated plants
- Cleaning process (pay attention to the cross-contamination with the cleaning products)
- Example of means to decrease and control cross-contamination :
  - o Production in campaigns :
  - o Sequencing rules

## 9. Cleaning and cleanliness measure

### 9.1. Cleaning

#### 10.1.1. General requirements for Cleaning

To maintain a hygienic condition in the food contact processing equipment and environment cleaning programs are to be defined and monitored.

It was established in section 9.2 Microbiological cross-contamination, that the risk of biological growth is low and thus sanitizing is not a requirement.

### 9.2. Cleaning agents and tools

Facilities, tools and equipment should be easily cleaned and, when possible, of a hygienic design. Cleaning agents are to be clearly defined and manufacture's instructions on their use should be followed.

### 9.3. Cleaning programs

Programs and schedule for cleaning should be created by the company including at least areas, equipment, method, frequency, person in charge of such tasks, monitoring, inspections of post-clean and pre starting where required. The cleaning of the equipment is also part of such programs.

### 9.4. Pest control

#### 9.4.1. General requirements

A favourable environment for pest activity should be avoided by establishing monitoring procedures.

#### 9.4.2. Pest control programs

A pest control program should be in place with a responsible person (or contractor) named for such activity. Such program should include target pests, schedule, procedures and trainings. The approved chemicals for each area is to be described in such program.

#### 9.4.3. Infestations

Prevention of product contamination by infested product should be done.

Materials stored outside should be protected from weather and pest damage.

#### 9.4.4. Monitoring and detection

Appropriate traps for pest detection should be arranged in key areas as part of pest monitoring as long as it does not damage products and facilities. The results of such monitoring is to be evaluated accordingly.

#### 9.4.5. Eradication

Eradication process should be applied as soon as infestation is verified. It is important to keep records of pesticide used and it should be handled only by trained personnel.

### 9.5. Waste Disposal

It is recommended to implement a procedure to manage all waste materials, which could be generated during the production on site.

Containers for waste and hazardous substances should be listed and clearly identified as such. They should be located in a specific location in the production area or/and in a warehouse to avoid any contamination of the final product(s). All waste disposals from manufacturing should comply with the locally applicable environmental protection laws.

Concerning labelling materials and/or printed packaging considered as waste, they should be destroyed or be recycled by ensuring that the trademark could not be reused. Their removal or their recycling should be performed according to the locally applicable environmental protection laws.

Drains should be of adequate size and located in production areas, as well as in warehouse locations (if necessary), in order to avoid any contamination of the final product(s). Their capacities should be sufficient to remove flow loads, when appropriate.

## 10. Personnel hygiene and employee facilities

### 10.1. General requirements

Personal hygiene needs should be defined depending on the risks and hazards related to a manufacturing area and the involved people in such areas are required to follow such requirements.

Management should provide appropriate resources for qualified supervisory and involved personnel to perform GMP activities related to finished articles, intermediate materials and food contact substances.

The operator must be informed about the final application, so that he/she is aware of the risk for the final consumer caused by his failure. The operator shall follow the specific defined processes and specifications laid down by the resin manufacturer. The company shall provide training in quality assurance requirements to all its personnel and temporary and external staff to a level appropriate to the operations. The effectiveness of the trainings shall be monitored and documented.

COMMITMENT : The entire workforce involved in the production of food contact resins, including all levels of management is committed to the objectives of GMP.

### 10.2. Personnel hygiene facilities and toilets

Availability of personal hygiene facilities should be in place in order to fulfil the established company's personal hygiene.

### 10.3. Staff canteens and designated eating areas

Staff canteens and designated areas for food consumption and storage should be defined in order to avoid potential product contamination.

### 10.4. Workwear and protective clothing

Appropriate and in good condition working cloths should be used by those working in product exposure areas.

### 10.5. Personal cleanliness

Employees working in food contact materials production should be required to properly follow hygiene procedures, such as washing their hands.

## 10.6. Personal behaviour

A policy containing personal behaviour requirements in the manufacturing of food contact products should be in place (e.g. smoking, eating, ...).

## 10.7. General precaution

Situation not defined in procedures: keep in mind the use of the resins. Any inappropriate situation should be discussed with the managers or the GMP responsible.

## 10.8. Training

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

# 11. Rework

In case rework is an option, all details about the material to be reprocessed must be documented, including initial rejection reason, product name, manufacturing date, batch number, expiry date, amount of material to be reworked. This will ensure traceability of reworked materials onto new batches of final products.

To ensure product safety, regulatory compliance, quality and traceability, attention must be given to the storage, handling and use conditions of non-conform material designated for rework.

# 12. Product recall procedures

Whenever food safety is at stake due to questionable quality of a product and/or its components or packaging materials, appropriate procedures shall exist and appropriate measures must be taken in order to enable product withdrawal. These include identification, tracking down and removing affected product from circulation and prevent its further use or processing.

An updated list of relevant contacts to use in a recall (customers, distributors, sales agents, authorities) must always be kept.

In case a recall procedure is necessary due to serious health threat, an assessment of the safety of other products manufactured under the same conditions should be carried out.

# 13. Warehousing

Raw materials and finished resins should be stored in conditions to prevent any deterioration of the material, and organized in such a way that identification labels are visible, contributing to an effective inventory management method (First In First Out / First Expired First Out).



Warehouse conditions should be observed in such a way that product's and packaging's integrity are not affected or damaged by temperature, humidity or stacking.

Keep waste material, cleaning and maintenance products stored apart from raw materials and finished resins. A specific segregated area should exist to store separately non-conform material.

Whenever surfaces in contact with finished resins are reused, like conveyor belts and containers, there should be a procedure in place that grants these surfaces are individually inspected and cleaned prior to reutilization,

The same inspection and cleaning procedure also applies to vehicles used for transport, prior to the loading of the finished resin.

If required by the organization, bulk containers and bulk tanks might be dedicated to specific food contact materials and / or products.

## 14. Product information

A descriptive title or a trade name, reference number and specific batch number identify each product.

On request of the customer, the resin supplier will provide written documentation (Declaration of Compliance, Statement of Composition or any equivalent written document) setting out the information which a customer will need to ensure compliance with Regulation (EC) 1935/2004, and food contact materials covered by specific measures (such as Regulation (EU) 10/2011, Directive 2007/42/EC, or national text, or 21 CFR 174-178 from US FDA...).

The Safety Data Sheets provided in compliance with REACH (Regulation (EC) No 1907/2006) are not considered to be sufficient for customers to ensure compliance with Regulation (EC) No 1935/2004 and other food packaging regulations.

## 15. References

## HARRPA Resins in FCM - GMP related documents

## EU Regulation related to GMP for FCM

- Regulation (EC) 2023-2006 on good manufacturing practice for materials and articles intended to come into contact with food  
<http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32006R2023&from=FR>
- Regulation (EC) 1935-2004 on materials and articles intended to come into contact with food  
<http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32004R1935&from=EN>

## US regulation related to GMP for FCM

- 21 CFR Part 174.5- General provisions applicable to indirect food additives  
<http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32004R1935&from=EN>
- 21 CFR Part 117: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food

## GMP guidelines for FCM from Professional associations

- XP ISO/TS 22002-1 : Prerequisite programmes on food safety (June 2010)
- UV EB Acrylate Resins Sector Group (UV EB)  
<http://www.pac.gr/bcm/uploads/gmp-cefic-uveb.pdf>
- European Printing Ink Association (EuPIA)  
[http://www.eupia.org/uploads/tx\\_edm/2016-03-31-EuPIA\\_GMP\\_4th\\_version\\_final.pdf](http://www.eupia.org/uploads/tx_edm/2016-03-31-EuPIA_GMP_4th_version_final.pdf)
- Association of the European Adhesive & Sealant Industry (FEICA)  
<http://www.feica.eu/cust/documentview.aspx?DocID=1769>
- Society of plastics Industry (SPI)  
[http://www.plasticsindustry.org/files/about/fdcpmc/fdcpmc\\_manuf\\_practice%20guidelines20120126.pdf](http://www.plasticsindustry.org/files/about/fdcpmc/fdcpmc_manuf_practice%20guidelines20120126.pdf)
- European council of the paint, printing ink and artists' colours industry (CEPE)  
[https://view.officeapps.live.com/op/view.aspx?src=http%3A%2F%2Fwww.cepe.org%2FEPUB%2F%2Feasnet.dll%2FGetDoc%3FAPPL%3D1%26DAT\\_IM%3D1037C0%26DWNLD%3D100802%2520GMP%2520Can%2520Coatings.doc](https://view.officeapps.live.com/op/view.aspx?src=http%3A%2F%2Fwww.cepe.org%2FEPUB%2F%2Feasnet.dll%2FGetDoc%3FAPPL%3D1%26DAT_IM%3D1037C0%26DWNLD%3D100802%2520GMP%2520Can%2520Coatings.doc)

## GMP guidelines for Food contact Packaging from Professional associations

- Consolidated Standards for Inspection: Food Contact Packaging Manufacturing Facilities AIB International (2010)  
[https://www.aibonline.org/aibOnline\\_/www.aibonline.org/Standards/Food\\_Contact\\_k\\_Eng\\_Man\\_web.pdf](https://www.aibonline.org/aibOnline_/www.aibonline.org/Standards/Food_Contact_k_Eng_Man_web.pdf)



- Guidance for Developing, Documenting and Implementing an SQF 2000 System – General Food Packaging Materials - Manufacture and Distribution
- Safe Quality Food Institute (2010)

<http://www.sqfi.com/wp-content/uploads/2000-Guidance-FoodPack.pdf>

- Global Standard for Packaging and Packaging Materials British Retail Consortium (2011)  
<http://www.brcglobalstandards.com/standards/packaging-and-packaging-materials/>
- PAS 223: Prerequisite programmes and design requirements for food safety in the manufacture and provision of food packaging British Standards Institute (2011)  
<http://shop.bsigroup.com/en/SearchResults/?q=PAS223>

#### **Company guideline for GMP :**

- Huntsman  
[http://www.huntsman.com/polyurethanes/Media%20Library/a\\_MC1CD1F5AB7BB1738E040EBCD2B6B01F1/Products\\_MC1CD1F5AB8081738E040EBCD2B6B01F1/Thermoplastic%20polyur\\_MDC92D212C2A5565FE040EBCD2B6B3E40/files/GMP\\_englisch\\_20\\_06\\_2013.pdf](http://www.huntsman.com/polyurethanes/Media%20Library/a_MC1CD1F5AB7BB1738E040EBCD2B6B01F1/Products_MC1CD1F5AB8081738E040EBCD2B6B01F1/Thermoplastic%20polyur_MDC92D212C2A5565FE040EBCD2B6B3E40/files/GMP_englisch_20_06_2013.pdf)