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GUIDELINES FOR GOOD MANUFACTURING PRACTICE FOR SYNTHETIC ORGANIC ION EXCHANGERS AND ADSORBENTS INTENDED FOR FOOD CONTACT APPLICATIONS

These industry guidelines have been drafted to support individual companies in the supply chain to establish their company specific manufacturing processes and procedures according good manufacturing practice, but don't replace the respective requirements set by Commission Regulations.

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About SOIA
SOIA is a sector group of Cefic, the European Chemical Industry Council
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Summary

Compliance with Article 3 of Regulation (EC) 1935/2004 - the Framework Regulation for food contact materials and articles- is the basis of the requirement for 'good manufacturing practice' in the production of materials and articles intended for contact with food.

Commission Regulation (EC) No 2023/2006 'on good manufacturing practice for materials and articles to come into contact with food' sets more specific requirements on good manufacturing practice, applicable to all food contact materials, including a specific Annex in regards printing inks. These GMP requirements are in place since August 1 2008.

The guidelines developed in this document are applicable to Synthetic Organic Ion Exchangers and Adsorbents (herein after referred to as IERs) subject to the COE Council of Europe Resolution ResAP 2004(3). These guidelines, applicable to the IER industry supply chain, do include the specific requirements as set by Regulation (EC) No 2023/2006. However, each individual company should carefully review Regulation (EC) 2023/2006 to ensure all relevant requirements are properly addressed for its own manufacturing operation.

'Good manufacturing practice' for production of food contact materials and articles follows a chain beginning at the approval and acceptance of the starting materials for IER production and ending when the materials and articles come into contact with food. These guidelines should be seen as a guide on how 'good manufacturing practice' principles can be established in order to help to consistently produce compliant food contact materials and articles rather than being a prescription.

Two stages can be considered:

- First: the stage of "design for compliance" during which a safe and organoleptically acceptable IER is developed with the intent to be compliant with the regulatory requirements for food contact.
- Second: the stage of commercial production during which regulatory compliance of the composition and possible migrants of materials and articles needs to be consistently ensured.

Three main concepts for 'good manufacturing practice' for production of IER for food contact are of primary importance:

- Creating awareness at all levels involved
- Maintaining compliance of the composition and possible migrants through effective contamination prevention
- Maintaining compliance of the composition and possible migrants through effective management of change procedures indicating potential changes in composition or contamination risk.

Subject guidelines are a general basis and details can vary depending upon the position in the supply chain.

1. Legal reference

Article 3 of Regulation (EC) 1935/2004 (The Framework Regulation)[1] clearly stipulates the objective for materials and articles intended to come into contact with food:

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

Regulation (EC) no 2023/2006 (4) on good manufacturing practice, defines more specifically the requirements in regards **good manufacturing practice**, as required by Regulation (EC) 1935/2004.

2. Application field

The guidelines for 'good manufacturing practice' described in this document apply to IER covered by the European Resolution AP (2004)3[2].

'Good manufacturing practice' for production of food contact materials and articles follows a chain beginning at approval and acceptance of the starting materials for IER production and ending when the IER come into contact with food.

3. Definitions

3.1 'good manufacturing practice':

According Regulation (EC) 2023/2006 following definition for good manufacturing practice has been established for food contact materials and articles (article 3(a)):

"good manufacturing practice (GMP) means those aspects of quality assurance which ensure that materials and articles are consistently produced and controlled to ensure conformity with the rules applicable to them and with the quality standards appropriate to their intended use by not endangering human health or causing an unacceptable change in the composition of the food or causing a deterioration in the organoleptic characteristics thereof."

[1] EC Regulation 1935/2004 on materials and articles to come into contact with foodstuffs
[2] European Resolution AP 2004(3) on ion exchange and adsorbent resins in the processing of foodstuffs

3.2 Starting materials and raw materials:

For the purpose of the guidelines developed in this document;

'Starting substances or starting materials' are any intentionally added substances that take part in or are present during the IER production.

'Raw materials' are any substances or materials that take part in or are present during the physical transformation of the polymers. Those include material recovered from a production process either in house or bought from an external converter.

3.3 Food contact material:

A material intended to come into contact with food or to come into contact with food after a suitable transformation or finishing process.

4. Is there still a need for 'good manufacturing practice' when ISO 9000 certification has already been established?

Generally, product specifications or specifications of starting materials and raw materials do not necessarily ensure the control over possible migrants as referred to in Article 3 of the Framework Regulation.

'Good manufacturing practice' adds a framework of additional precautionary measures to facilitate meeting the regulatory requirements, acknowledging that typical specifications cannot comprise the full set of legal requirements for the intended use.

In other words; ISO quality systems help to ensure that products are produced according to documented procedures and specifications, whereas 'good manufacturing practice' aims to ensure that products are consistently suitable for the intended use.

ISO 9000 procedures can thus be an excellent carrier for 'good manufacturing practice' but should not be confused with 'good manufacturing practice as such'.

5. What are the requirements for the intended food contact use?

The Framework Regulation clearly highlights that the safety, composition and organoleptic integrity of the treated food is a regulatory requirement. This aspect is repeated in the definition of GMP in Regulation 2023/2006.

The entire composition of an IER and its possible migrants must thus be designed and consistently maintained so that meeting the regulatory requirements in terms of health, safety and organoleptic characteristics of the treated food is consistently ensured.

Two stages can be considered:

First: the 'design for compliance' stage in which a safe and organoleptically acceptable IER is established through:

1. Compliance with European Resolution AP (2004)3.
2. Safety assessments, satisfying the requirements of Article 3 of EC Regulation 1935/2004.

Second: at the stage of commercial production, during which regulatory compliance of the composition and possible migrants of materials and articles needs to be consistently ensured, very strict management of change procedures, as well as effective contamination prevention procedures, are of primary importance.

Potential composition changes need to be indicated and a judgment -if necessary supported by new safety assessments - needs to be made to confirm continued compliance with food contact legal requirements.

6. Scope of 'good manufacturing practice'

'Good manufacturing practice' is directed to consistently meet the requirements of the intended use and consequently the details in implementation are application dependent.

'Good manufacturing practice' for food contact materials and articles follows a chain beginning with the approval and acceptance of the starting materials for polymer production and further covering production, packaging, warehousing and shipment all the way down the polymerisation, the conversion and the supply chain.

Article 2 of Regulation 2023/2006 defines the scope as follows:

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

Building on the above the following scope can be drawn:
'Good manufacturing practice' for materials and articles for food contact is about:

1. Quality assurance system and quality policies
2. Management leadership and personnel
3. Hygiene policy (if relevant depending on the position in the supply chain)
4. Documentation, labelling, document retention and traceability
5. Production
    a. Starting and /or raw material specifications and acceptance
    b. Contamination prevention
    c. Management of change
    d. Storage packaging, warehousing and transportation

6. Quality control and specifications
7. Work contracted out
8. Complaint handling, product recall and incident management
9. Regular internal and supplier audits.

7. Guidelines for 'good manufacturing practice'

The guidelines given below are general guidelines and may vary depending upon the position in the supply chain. Items 1 to 9 provide more guidance than what is legally required by Regulation (EC) 2023/2006.

It is strongly recommended to review carefully the requirements set in this GMP Regulation.

7.1 Quality assurance system and quality policy:

- There is a quality policy which is adequate to consistently produce IER for food contact in compliance with the applicable regulations.
- There is an effective quality assurance system involving the active participation of management and personnel.
- A quality control department must exist with responsibility and authority to independently approve/reject all materials in the process.

7.2 Management leadership and personnel:

- Management responsibilities for 'good manufacturing practice' implementation are assigned, defined and documented.
- The personnel supervising or performing the manufacture or control of food contact IER should have the education, training and/or experience to perform the assigned functions.
- Training of personnel shall include training on 'good manufacturing practice'.

7.3 Hygiene policy:

- If relevant, depending on the position in the supply chain, adequate and appropriate hygiene measures are maintained for personnel, factories, warehouses and transportation.
- If relevant, depending on the position in the supply chain, a pest control program should be maintained or the justification for lack of one should be documented.

7.4 Documentation, labelling, document retention and traceability:

- There is a system in which product formulation, operating procedures, operating windows, product release specifications and other critical information shall be documented.
- In a production plant where food contact IER are produced as well as non-food contact material, and when there is a risk that cross contamination can harm the quality of the food contact material and articles, production of food contact IER shall be flagged.

- There are procedures to cover traceability from incoming starting material to outgoing food contact IER. Those procedures also take into account the use of raw material recovered from a production process, and the recording and traceability of their use.
- Major equipment, transfer lines, containers and tanks that are used for processing, filling or holding food contact IER are identified either by labelling or by electronic control systems to indicate contents, batch designation, control status and other pertinent information.
- Appropriate documentation on quality critical items will be maintained as needed.

7.5 Production

Starting and/or raw material specifications and acceptance:

- There is a procedure to approve suppliers of starting - and raw materials. These procedures can contain different components depending on the position in the supply chain.
- There is a procedure to approve starting- and raw materials. Only approved materials are used.
- Starting materials are of a good technical quality as regards the purity criteria.
- Starting materials should be verified for acceptance before use.
- Starting and raw materials must be stored and handled in a manner which prevents their mix-up and/or adulteration.
- Materials not meeting the agreed acceptance criteria are properly identified and controlled to prevent misuse.
- Water that comes into contact with the food contact IER should be of suitable quality.

Contamination prevention:

- There is an adequate contamination prevention procedure based on risk assessment.
- The equipment and set up are adequate to preclude cross-contamination between materials for food contact and materials for non-food contact or their ingredients.
- There are effective transition procedures such as buffering or cleaning to avoid cross contamination when transitioning from non-food contact to food contact products (additive tanks, pipes, silo's,...).
- There should be a physical separation or a control system to segregate raw materials and product that has been released for use or distribution from material pending release, non conforming materials or product returns.
- Procedures are in place to assure that transfer, packaging or loading operations are conducted in such a way as to avoid product contamination.

Management of change

- Operation procedures and process operating windows have been established and documented. There is a management of change procedure in case operating procedures have to be changed. The management of change procedure is capable of detecting and indicating potential changes in the composition or increased risk of contamination.

- Changes in product formulations, starting and/or raw materials or suppliers of these materials are subject to a management of change.
- There are documented procedures to consider the impact of such changes on the final product quality, performance, composition and regulatory compliance status.

Storage, packaging, warehousing and transportation:

- There is sufficient and well managed storage for starting and/or raw materials.
- Storage conditions are such that they will avoid adulteration of the food contact materials or articles.
- Silo's and bulk trucks can either be dedicated equipment receiving only food contact materials or alternatively there are effective measures or procedures (such as cleaning or transition procedures) to ensure that the containers do not contain any products or contaminants that are not compatible with the intended use of food contact.
- There are procedures in place to ensure correct labelling.

7.6 Quality control and specifications

- Documented specifications exist for starting and/or raw materials and finished products.
- Starting and/or raw materials and finished products should be monitored to verify their compliance and conformance with specifications.
- Every food contact material product code has one unique specification.
- IER used in food contact should be manufactured according to pre-defined specifications.

7.7 Work contracted out

- Any contracted out manufacturing operation or operation linked thereto (such as e.g. warehousing) and should be performed according to 'good manufacturing practice' comparable to the one assured by the own operation.

7.8 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 procedure in place to investigate product contamination.
- There are measures in place to ensure that non-conforming or recalled products are not released for food contact use without extensive investigation and proper authorisation.

7.9 Regular internal and supplier audits:

- There is a procedure in place to ensure regular internal audits or self assessments in order to monitor the implementation and respect of 'good manufacturing practice'.

Comment:

This document from March 2011 was required to implement the provisions of Regulation 2023/2006, which requirements apply as of August 1 2008.