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Ion Exchange & Adsorbent Resins

CODE OF PRACTICE[1] FOR SYNTHETIC ION EXCHANGE AND ADSORBENT RESINS USED IN THE PROCESSING OF FOODSTUFF

WORKING DOCUMENT

EDITION

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[1] This Code and included Guidelines are of a voluntary nature. Individual companies may decide to apply these either in full or partly, or not, according to their own judgement.

SOIA
Rue Belliard 40 box 15 B-1040 Brussels Belgium
Tel. +32.2.436.94.42 can@cefic.be http://soia.cefic.org/
A sector group of Cefic
European Chemical Industry Council - Cefic aisbl
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Introduction

Historical Background

The use of synthetic ion exchange and adsorbent resins in high purity applications has long been established. This has seen these products in widespread use in applications with the highest possible requirements for purity in the electronics and nuclear industries and for the production of municipal and domestic potable water, food and pharmaceuticals. The resins required for these markets have to undergo special production techniques and/or special post treatments to differentiate them from industrial grade resins and ensure that in service they provide no contamination that can constitute a risk to human health.

This code of practice addresses specifically the production and use of these synthetic resins and synthetic adsorbents within the European food industry where the resins are in direct contact with the food material. With lack of specific regulations for bioprocessing applications, resins meeting food contact requirements are typical used in bioprocessing applications.

Ion exchange resins are used in a wide variety of applications and have long been established in some parts of the food industry, for example in the sugar and sweetener industries, where they are involved in two major processes of deashing and decolourisation. These remain very significant markets for resins. However, there are many more applications and the number of applications and installations continues to grow. Most of these processes make use of well-established resin types, while others require new products to be developed.

While synthetic ion exchange resins and adsorbents have always been considered "intrinsically safe", it is important both to food manufacturers and their consumers that safeguards and recognised specifications are in place to ensure quality is guaranteed and that no substances migrate from the synthetic ion exchange resins or adsorbents into the food which could cause harm.

The ion exchange industry recognises the need to have a fully coherent and united approach to this subject to provide the correct level of confidence, both to the food manufacturers and to the consumers, in the safe nature of our products.

In the recent past the Council of Europe resolution ResAP(2004)3 which the main suppliers of synthetic ion exchange resins (DuPont, Finex, Lanxess, Purolite, and Resindion) have played an active part, both in drawing up the initial document and in ensuring this resolution has been kept updated to cover changes in production processes and new substances or resins.

Today in the European community, there are no harmonized directives or regulations in place for ion exchange and adsorbent resins used in the processing of food materials.

With this code of practice, the previously named resin manufacturers, who are all active members of Cefic, have drawn up this Code of Practice to supply additional information to the ion exchange resin and adsorbent end users and those involved in regulating the use of these products. It is meant as an important supplement to the ResAP(2004)3.

European Code of Practice for Synthetic Resins / Adsorbents

All ion exchange coming into contact with food have to comply with Article 3 of the Regulation (EC) 1935/2004 (replacing Framework Directive 89/109/EEC) which states that migrants must not endanger human health.

This code of practice will provide food manufacturers and consumers the protection and confidence that ion exchange resins and adsorbents supplied in Europe which are in contact with food materials will comply with the Framework Regulation above.

This Code of Practice is of voluntary nature, each company taking their individual decision to apply it (partially or in full). It is not an exclusive system and companies may decide to use other ways of ensuring the protection of Health, Safety and the Environment.

Companies when applying this Code of Practice along the chain of supply should ensure that the way it is applied is in strict compliance with competition law.

This code of practice applies to ion exchange and adsorbent resins which are used in the processing of foodstuff and come in direct contact with foodstuff. The use of ion exchange resins and adsorbents are used principally for purification (removal of contaminant), concentration, conversion, separation, etc.

Synthetic Ion Exchange Resin and Adsorbent Production

Both synthetic ion exchangers and adsorbent are polymeric in nature, but there are differences in the products.

The synthetic ion exchange resins used in contact with food materials are in insoluble bead form and comprise of a polymer backbone which is activated to give its ion exchange capability.

The synthetic adsorbents are similar. They are also in insoluble bead form, but the polymer structure is modified to give the beads a very large surface. Hence, it is primarily a surface attraction which captures species, as most adsorbents are not activated. However, some products are given a low level of ion exchange functionality to assist this capture at the bead surface or to help with possible regeneration of the adsorbent.

When produced the activated resins and adsorbents can then be converted to different ionic forms to those produced. Hence some cation resins are available in sodium or hydrogen forms (other forms also exist). Anion resins are often encountered in chloride, sulphate, hydroxide and free base forms.

The final process is usually a post treatment stage which improves the purity and cleanliness of the resin. While all resins are post treated, the type of post treatment is dependent on the application. Final QC analysis and testing are conducted to ensure products meet the desired quality.

Therefore, from the above description the production process consists of four stages, polymerisation and activation, conversion and post treatment. The following section explains these four stages in more detail.

Stage 1: Base Polymer

The two polymers primarily used in the production of ion exchange resins and adsorbents are styrene or acrylic based. While polystyrenic based products far outnumber the number of polyacrylic based products, both are used within the food industry.

The products are produced by suspension polymerisation, this was primarily a batch process in stirred reactors for many years, and many products are still produced by this means. However, new techniques have since been established for some special grade products where a more continuous process is now employed.

In all cases the polymerisation process requires a cross linking agent to form the beads and the process incorporates polymerisation aids, and stabilisers which help form the stable bead structure.

Reference is often made to two types of polymer structure, the term "gel" and "macroporous" structure are often encountered when looking at different types of ion exchange resins. Gel resin beads are made from a single gel phase; the beads are solid and usually translucent to light. They have high breaking weights and are physically strong, but have a small surface area. Macroporous resins have a porogen introduced during the polymerisation stage. This material plays no part in the chemical reaction but produces a bead structure with pores (holes) within the bead, therefore increasing the surface area in the bead and offering other changes in the characteristics of the resin (better access to ion exchange sites, better resistance to osmotic shock, attrition, etc.).

While ion exchange resins are made from both resin structures, as you might expect, synthetic adsorbents are usually produced with a macroporous structure. This is to provide the large surface area required.

As the substances used to induce resin porosity do not play a reactive part in the production of the polymer they are easily washed from the beads.

In the production of the polymer beads, for food grade and other high purity products these are sometimes specially treated as they are inert and in a robust form. This allows the polymer to be cleaned before moving forward to activation stages.

Stage 2: Activation

The polymers produced vary considerably depending on the type of activation to be carried out on the resin and final product to be produced. However, in general terms, in the vast majority of cases within the food industry, activation will result in either the production of cation resin or anion resin. However, some specialist resins with unique functionality are also produced i.e. chelating resins etc.

Within the commonly encountered cation and anion categories these can be split further to produce the following resin types:

Cation Resin Types	Strong Acid Cation Resins
	Weak Acid Cation Resins

Anion Resin Types	Strong Base Anion Resins
	Weak Base Anion Resins

Weak acid cation resins are normally manufactured from polyacrylic polymers, and strong acid cation resins from polystyrenic polymers. However, both weak and strong base anion resins can be supplied either based on polystyrenic or polyacrylic polymers.

The activation of cation resins is relatively straight-forward and is primarily a single stage process. The activation of anion resins is a more complicated procedure and requires a two stage process. This is to generate a "handle" to be applied to the polymer chain to allow the active group to be added.

Activation of a strong acid cation resin provides a sulphonic acid group to carry out the cation exchange process while a weak acid cation has a less strongly acidic carboxylic acid group to carry out the ion exchange process.

The activation of anion resin involves the addition of an amine group to the resin and depending on the amine applied this not only determines if the anion resin is weak base or strong base, but also it has an effect of the chemical performance, and thermal stability of the final resin. End users will therefore not only see reference to weak base and strong base anion resins, but also strong base resins are also classified as being type 1, type 2 etc. depending on which of a number of different amines is applied to achieve their chemical performance.

For example, within the food industry, nitrate removal resins use a completely different amine to conventional anion resins to give them their improved nitrate selectivity.

<u>Stage 3: Conversion</u>

Conversion of ion exchange resins to different ionic forms is carried out for a number of reasons listed below.

1. Conversion between different ionic forms can cause the resin to swell or shrink and this can be part of the clean-up procedure of the resin manufacturer.

2. The resin producer can convert the resin into an ionic form which is more stable, so that the resin can be stored longer without affecting its performance in service and maintains the resin in a cleaner state. (Please note resin manufacturers usually provide guidance on pre-treatment of their resins before introducing them into any food contact application.)

   For this reason, food contact applications often specify that strong acid cation resins are supplied in the sodium form and strong base anion resins in the chloride form.

3. End users sometimes specify a specific ionic form for the application the resins are to be applied.

Stage 4: Post Production Treatment

In addition to the specialist production techniques employed in the production of food contact resins and adsorbents, each resin manufacturer also applies their own post treatment techniques. These are proprietary treatments developed by the manufacturer to ensure the resins meet the required food grade standards applicable to the product when produced.

They also ensure that, if the products are transported and stored correctly on site before installation, and then treated in line with the manufacturer's instructions (see sections on storage and pre-treatment on site) when placed in service, the products will meet the end user requirements.

For synthetic adsorbents some products are supplied with specialist additive to maintain purity in storage prior to use.

No synthetic ion exchange resin or adsorbent should be placed in service in a food contact application without first checking that the material has the necessary food contact compliance and that in entering service the product is in an acceptable clean state.

Packaging / Storage

All resin manufacturers offer a variety of packaging. This packaging is designed to prevent both contamination of the product during transport and in storage, prior to use, and also to stop the resins from drying out (if supplied wet), or from adsorbing moisture if the product is supplied dry, or partially dried, for non-aqueous applications. For the vast majority of food grade applications the ion exchange products and adsorbents are supplied wet.

It is particularly important for food grade products and some other specialist applications that the packaging offered is fit for purpose and in some cases the end user, in conjunction with the resin manufacturer, agrees their own specification for specialist or enhanced packaging of the product following production.

The packaging should never be opened prior to the products being installed for use in the application. It is recommended that the resin is left in the original packaging, usually pallet mounted until they are required. Depending on company policy, clients wishing to check the product as supplied should request a pre-shipment sample from the same batch and full certificates of conformity or certificates of analysis.

The storage of resins on site is also critical. Each manufacturer provides their own recommendations, both on the storage conditions and shelf life of their products if stored correctly, to ensure the resins remain in the best condition at all times.

Pre-treatment on Site

All applications for synthetic ion exchange resins and adsorbents will require some kind of pre-treatment when removed from the original packaging and after loading into the plant. Sometimes these are relatively simple on industrial plant, while others are more complicated and require longer commissioning period. For all food grade products there is a specific manufacturers pre-treatment procedure.

First, before installing the resin, all end users should ensure they check that all the resin is correctly labelled with the correct product name. They should record the batch number of the resins installed in each unit filled. Please remember products can be supplied from more than one batch, particularly on large installations.

Depending on the application some resins may require an extended backwash to classify the bed (ensuring optimum pressure drop is achieved) and a specified rinse to drain. Other products may require in addition a full regeneration and extended rinse to drain before placing in service. Some applications require even further specialist treatment/conditioning. In all cases in food or potable water applications, the end user should ensure he has the latest up to date recommendations from the resin manufacturer for his application. He should follow those instructions fully and if he has any problems in carrying out the requirements as defined, then he should consult the manufacturer.

The clean-up procedure normally defines the treatment required by the product to meet its expected performance and food grade quality on direct delivery from the manufacturer. Unfortunately, the manufacturer has no control over the length of time, or how the resin is stored and in specific cases, how it is transported prior to use following delivery to the end user. Therefore, it is important that after the pre-treatment conditioning stage, that the end user verifies the performance by taking samples and testing fully the treated material before placing the product in full service.

On occasions when long term or incorrect storage has been employed some additional conditioning is required beyond that normally specified and again the manufacturer should be consulted for assistance. This may involve just extending the rinse period, special cycling, or further regenerations / exhaustion of.

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Ion Exchange & Adsorbent Resins

Article 1 - Subject matter and scope

1.1. This Code of Practice describes how compliance with the Regulation (EC) 1935/2004 and subsequent amendments can be demonstrated for ion exchange and adsorbent resins used in the processing of foodstuffs and coming in direct contact with foodstuff[2].

1.2. Ion exchange and adsorbent resins, are synthetic organic macromolecular components which can be used in the processing of foodstuffs to bring about exchange of ions or adsorption of foodstuffs constituents.

Main applications, resins are used in:

1. Water treatments:
   a. Softening & deionization
   b. Condensate treatment
   c. Process water treatment
   d. Drinking water treatment
   e. Waste waters treatment
2. Hydrometallurgy:
   a. Recovery & concentration of noble metals
   b. Separation of rare earth metals and of heavy metals
3. Food industry
   a. Sugar & sweetening agents
   b. Wine-making
   c. Fruit juices
   d. Citric acid
   e. Protein recovery
   f. Amino acid separation
   g. Enzyme Carriers
4. Dairy industry
   a. Milk whey demineralization, deacidification and decolourisation
   b. Purification of lactose
   c. Preparation of pure casein
5. Chemical process industry
   a. Catalysis
   b. Purification of chemicals
6. Pharmaceuticals:
   a. Separation of alkaloids, antibiotics, vitamins, etc.
   b. Carriers in the processing of pharmaceuticals with delayed action.
   c. Life science purification (e.g. protein purification etc.)
7. Bioprocessing applications:
   a. Used as processing media
   b. Carriers for enzymes.

[2] Foodstuffs are as defined in Regulation(EC) No 178/2002 – see glossary

1.3. Depending on their chemical composition and intended use, ion exchange and adsorbent resins can be classified as follows:

A) Ion exchange resins

Ion exchange resins have a polymer structure bonded to ionic groups. The nature of the ion exchange resin is greatly influenced by the network structure of its polymer matrix.

For most ion exchange resins, the matrix consists of copolymers made of:

- styrene and divinylbenzene;
- methacrylate and divinylbenzene (acrylate and divinylbenzene);
- methylmethacrylate and divinylbenzene (methylacrylate and divinylbenzene).

However, there are also some specialist synthetic, polymer, ion exchange resins, manufactured for specialist applications in the field of Life Sciences such as:

- agarose (a polysaccharide polymer) extracted from seaweed, widely used in purification applications and can be used both functionalised or non-functionalised.

Ion exchange resins are divided into:

1. Cationic, main ionic groups:
    a. Strongly acidic: $-SO_3^-$
    b. Weakly acidic: $-COO^-$
2. Anionic
    a. Strongly basic: -NR3+
    b. Weakly basic: -NH2; -NHR; -NR2

    There are two types of strongly basic anion exchange resins:
    - “TYPE I” has the strongest basicity but lower capacity
    - “TYPE II” has somewhat weaker basicity but higher capacity

3. Special Ion Specific Active Groups - e.g. chelating

B) Adsorbent resins

Adsorbents resins are spherical crosslinked polymers with porous structure. Similar to the ion exchange resins described above, but with no ion-exchange groups or only a limited amount of functional groups present, the primary mechanism of action is based on the adsorption of organic compounds on the surface due to hydrophobic interactions and/or by size exclusion effect.

1.4. This Code of Practice shall not apply to:
   a. Inorganic ion exchangers
   b. Polymers used in the processing of foodstuffs and which don't meet the definition of ion exchange and adsorbent resins.

Article 1bis - Definitions

1.1. Monomers and starting substances are substances undergoing polymerisation, which includes polycondensation, polyaddition or any other similar process, to manufacture synthetic macromolecules (polymers).

1.2. Modifiers are substances which are used to modify polymers to give them specific properties, and which are chemically bound to the polymer.

1.3. Additives are substances added to the polymers to achieve a technical effect but which are not chemically bound to the polymer.

1.4. Aids to polymerization are substances which directly influence the formation of polymers and constitute a separate class of substances planned to be regulated by specific rules. They include, for example: Accelerators, Catalysts, Catalyst deactivators, Catalyst supports, Catalyst modifiers, Chain scission reagents, Chain transfer or extending agents, Chain stop reagents, Cross-linking agents, Initiators and promoters, Molecular weight regulators, Polymerisation inhibitors, Redox agents, ….

1.5. Polymerization aids are substances used to provide a suitable medium in which polymerisation occurs, but are not expected to present in the final product other than as trace impurities. They include, for example: anti-foam reagents/degassing agents, blowing agents, buffering agents, build-up suppressants, dispersing aids, emulsifiers, flow control agents, nucleating agents, pH regulators, solvents, surfactants, suspension agents, stabilisers, thickening agents, water treatment reagents,….

Article 2 - Good Manufacturing Practice (GMP)

2.1. Ion exchange and adsorbent resins shall be manufactured in compliance with the Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food.

2.2. Ion exchange and adsorbent resins shall be manufactured in compliance with the Regulation (EC) No 2023/2006 on good manufacturing practice (GMP) for materials and articles intended to come into contact with food. GMPs can be company specific, but for reference, SOIA, the ion exchange and adsorbent resins industry sector group has developed a GMP guidance document.

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Ion Exchange & Adsorbent Resins

Article 3 - Lists of authorised substances

3.1. Those substances referred to in Article 4 may be used in the manufacture of ion exchange and adsorbent resins intended to come into contact with foodstuffs subject to the conditions and restrictions specified therein. The substances covered belong to the following categories:

- Monomers and other starting substances, modifiers, additives, chemical converters

Substances to be used in the manufacture of resins:

- Monomers, starting substances and additives stated in the Council of Europe Resolution ResAP 2004(3).

- Monomers, starting substances and additives listed in Annex I Table 1 of the Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food or which have received a favourable opinion by the European Food safety Authority or an equivalent competent scientific body

- Salts (including double salts and acid salts) of aluminium, ammonium, barium, calcium, cobalt, copper, iron, lithium, magnesium, potassium, sodium and zinc of authorised acids, phenols and alcohols are considered authorised. Specific migration limits stated in ResAP 2004(3) apply to the cation components of these salts.

- Mixtures of substances stated in ResAP 2004(3).

- Oligomers and natural or synthetic macromolecular substances, as well as their mixtures, if the monomers or starting substances used in the synthesis are stated in ResAP 2004(3).

The following substances have not been included in ResAP 2004(3):

- Aids to polymerization
- Polymer production Aids (e.g. solvents)
- Non-intentionally added substances (NIAS) e.g. impurities, degradation products.

These substances shall be assessed in accordance with internationally recognized scientific principles on risk assessment in order to demonstrate compliance with Article 3 of the Regulation 1935/2004 on materials and articles intended to come into contact with food.

Monomers, starting substances and additives not listed in Technical document 1 or in Annex I Table 1 of the Regulation (EU) No 10/2011 as amended.

Compliance with Article 3 of the classification and labelling Regulation (EC) 1935/2004 can be established if such substances meet the following criteria:

a) They are not classified as class 1 or 2 ‘mutagenic’ ‘carcinogenic’ or toxic to reproduction’ according to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
b) Their migration into food or food simulant is not detectable at a LOD of 10 ppb.

If not compliant with above two points, a substance can be qualified using an assessment in accordance with internationally recognized scientific principles on risk assessment.

Substance specifications
Substances to be used in the manufacturing of resins shall be of a technical quality and purity suitable for the intended application of the resins.

Article 4 - List of substances used in the production of ion exchange and adsorbent resins

Monomers, starting substances and additives listed in list 1 and 2 can be used in the manufacturing of synthetic resins.

- List 1 of substances used in the manufacture of ion exchange and adsorbent resins: list of substances assessed and approved by Partial Agreement member states

- List 2 of substances used in the manufacture of ion exchange and adsorbent resins: list of substances not yet assessed and not yet approved by Partial Agreement member states

Explanatory note
A number of the monomers and other starting substances currently used have not been fully assessed by SCF/EFSA, mainly because they are specifically used for ion exchange adsorbent resins. In order that they can continue to be used, they must have authorisation by at least one member state or be listed by the FDA. It is intended that the substances, which are used and are not on SCF Lists 0-4, will be subjected to toxicological testing or exposure assessments as described above.

In addition to those substances in the list, any substances which have an SCF or EFSA opinion (list SCF 0-4) may be used for the manufacture of the ion exchange and adsorbent for direct food contact, subject to any restrictions applicable to them.

The current list of monomers and other starting substances reflects those currently used to manufacture ion exchange and adsorbent resins, which are in contact with food. Industry reserves the right to use any fully evaluated (SCF 0-4) substance, but not-listed in list, in future developments, as an SCF/EFSA opinion exists. As this list is regularly updated these substances, will eventually appear on a future revision.

Article 5 - Migration testing and Methods of Analysis

Ion exchange and adsorbent resins for direct food contact resins should be subjected to AFNOR test T 90-601.

5.1. Food simulants

Water (<0.3 ppm TOC, <0.5 microSiemens/cm) may be used for testing water and aqueous food (nonacidic, non-alcoholic, non-oil in water emulsion).

Ethanol 15 per cent may be used for testing alcoholic food with alcohol content up to 15 per cent

Acetic acid 3 per cent may be used for acidic food with pH<4.5.

Ethanol 50 per cent may be used for alcoholic food with alcohol content >15 per cent or oil in water emulsions.

5.2. Elution procedure

Resins should be pre-treated prior to testing in accordance with the instructions of the manufacturer.

Follow the elution test procedure as defined by AFNOR T90-601:

- 100 mL of the resin to be tested are placed in a test column and rinsed with 20BV (Bed Volumes) of test solution (water or food substitute as defined in table 2.2) at a flow rate of 10 BVH (Bed Volumes / hour) and at ambient temperature.
- Let the closed test column stand for 24 h; then rinse the resin 5 times with 1 BV of test solution at a flow rate of 5 BVH. The five individual fractions of 1 BV are collected for testing.

The test temperature should be based on the application of use.

5.3. Migration testing

When using water as feed solution, resins should be tested for total organic carbon (TOC) according to AFNOR method T 90-601. All five bed-volumes prepared should be tested for TOC in order to demonstrate a decreasing release of organic carbon from the first through to the last bed-volume. Total organic carbon in the fifth bed-volume should not exceed 1 mg/kg; the total TOC in the combined five bed-volumes should not exceed 10 mg/kg.

For substances with a Specific Migration Limit (SML), specific migration into water or the relevant food simulant should be determined under the typical conditions of use following the procedure as described in AFNOR T90-601. The food simulant samples collected in the fifth bed-volume should be checked for specific migration. These should not exceed the limits set out in chapter 4 of this Technical Guide. Specific migration should be determined by a method of analysis validated at the level of the specific migration limit.

For substances with a QM restriction, the residual quantity of specific substance should be determined in the resin. The residual quantity should not exceed the limits set out laid down in chapter 4 of this Technical Guide.

To verify compliance, specific migration testing is not compulsory if it can be demonstrated by calculation, that by assuming complete migration of the residual quantity of a substance, the specific limit of migration of that substance will not be exceeded. Alternatively, the specific migration can be estimated with validated migration models that are constructed such as to overestimate real migration.

5.4. Mathematical modelling and Screening

If it can be shown by mathematical modelling, calculation or other screening methods, that the restrictions for substances laid down in this Technical Guide cannot be exceeded, no testing for compliance with these restrictions is necessary.

Article 6 - Declaration of compliance (DOC)

The written declaration of compliance shall contain the following information:

6.1. The identity and address of the manufacturer or business placing the ion exchange resins and adsorbents on the market.

6.2. The identification of the synthetic ion exchange resins and adsorbents.

6.3. The date of the declaration.

6.4. Confirmation that the ion exchange resins and adsorbents meet relevant requirements laid down in the Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food.

6.5. Confirmation that the ion exchange and adsorbent resins meet the requirements of the Council of Europe resolution ResAP(2004)3 in conjunction with this COP.

6.6. Compliance that the place of manufacture has and its production are covered by an internationally recognized and certified Quality Assurance System.

6.7. Compliance to the Regulation (EC) No 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food.

Notes: The declaration of compliance is valid based on the following conditions of use:

- When resins arrive on site, it is preferable to install the resins and place in service as soon as possible, complying with the other requirements below. When they have to be stored on site they must be stored correctly in line with the manufacturers recommendations preferably in their original packaging, out of direct sun light, and therefore indoors and away from extreme temperatures.

- The manufacturers recommendations for pretreatment of the resin in the specific application are followed. These are available from each manufacturer and may differ by manufacturer, resin and application. Resins held in store on site prior to use may require additional pretreatment depending on the storage time and conditions.

- When first placing the resins in service, the end user must satisfy themselves fully, that the first batch of treated product meets their requirements by comprehensive testing of the product produced by the resin and before proceeding with further production.

- The end user should have installed downstream of the resin column(s) a filter. This is to prevent contamination of the food material in the event that there is a failure in the collection system (releasing some resin) or to remove any fine particles that can be released from the bed due to degradation. Degradation is normally related to the age of a resin and/or the regeneration and service operating conditions in the specific application.

- End user must operate the resins in line with manufacturers recommendations, with regard to maximum operating temperature / regeneration conditions etc. Oxidizing agents will damage all synthetic resins and hence end users must also be careful with any sterilization procedures they adopt on their plant and if they sterilize the resins at any stage, what procedure/chemicals are used.

- Chemicals of the correct purity for regeneration should be used to ensure no contamination is derived in the food material from these regenerants.

Article 7 - Operating conditions, regeneration and disinfection

7.1 The producer on an ion exchange or adsorbent resins should develop guidance for users down the supply chain for a safe use of the materials including:

- Conditions for conditioning and starting an ion exchange or adsorbent resin unit within a food processing chain
- Conditions for the regeneration of exhausted ion exchange resins including the nature and where relevant purity of the regenerating agents.
- Operating conditions of ion exchange and adsorbent resins including temperature of processing, food solution flow, limitations, exhaustion, …
- Conditions for the disinfection of the ion exchange or adsorbent resin in case such an operation becomes necessary, including the nature and where relevant purity of the disinfection agents.
- Conditions of disposal of ion exchange resins

7.2 The migration tests described in article 11 or deemed necessary for the risk assessment must be performed after conditioning and regeneration as described in the guidance mentioned at point 1.

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For more information please contact:
Caroline Andersson, Sector Group Manager, Cefic,
+32 2.436.94.42 or can@cefic.be.

About SOIA
SOIA is a sector group of Cefic, the European Chemical Industry Council
https://soia.cefic.org/