



**EUROPEAN REGULATORY REQUIREMENTS FOR SYNTHETIC ORGANIC
ION EXCHANGE RESINS AND ADSORBENTS USED IN FOOD PROCESSING AND
POTABLE WATER PRODUCTION**



July 6, 2016 - Cambridge

Agenda

- Introduction Cefic-Soia
- Ion exchange and adsorbent resins (IER) used in food applications:
 - Council of Europe Resolution ResAP 2004(3)
Update
- Ion exchange and adsorbent resins (IER) used in potable water market

Who is SOIA?



Synthetic Organic Ion Exchangers and Adsorbents Group (SOIA):

- is one sector group of **Cefic** – The European Chemical Industry Council
- **Cefic**: - Association founded in 1972 and based in Brussels representing 29,000 small to large European chemical companies
 - Committed partner to EU policy makers, facilitating dialog with industry on technical and regulatory topics
 - Approximately 100 sector groups within Cefic
- Meeting twice / year on regulatory topics related to ion exchange and adsorbent resin
- Members are EU ion exchange and adsorbent resin manufacturers:

Cefic – Belgium:

Caroline Andersson

Dow – Germany:

Marie-Rose Diebold

Finex Oy – Finland:

Niina Lehtonen

Lanxess – Germany:

Katrin Wieland

Purolite – UK:

Brian Windsor

Resindion Srl – Italy:

Valentina Scilletta

This paper / lecture was written with input from all members.

What does SOIA?

Key issues include:

- Council of Europe (COE) Resolution ResAP (2004)3 on ion exchange and adsorbent resins used in the processing of foodstuffs
- National Legislation monitoring in food and potable water production
- EU Legislation monitoring (REACH, Plastics Implementation Measure (PIM), etc.)
- Other regulatory topics

Food Grade / Potable Water Market



Food Contact Compliance:

- Compliance = self certification
- Required for applications in:
 - Food (neutral, acid pH, alcoholic, dairy, etc...)
 - Water for beverages or food production
 - Drinking water using IER in cartridges

Potable Water Certification:

- Certification = third party
- Required for applications in:
 - Municipal water
 - Domestic water softeners

Food Grade Resins – Council of Europe Resolution



ResAP 2004(3)

2012 at SCI Conference reported:

- Belgian authorities in the lead to update this resolution
- Resolution will possibly taken into Belgian law

Today:

- Still not agreed by every state
- not expected to be approved before 2017

Council of Europe Resolution Proposed Changes (1)



Extension Field of Application

- Currently covers production of food stuffs

- Extension to the bioprocessing field to cover the use in the manufacturing process of pharmaceutical products:
 - pharmaceutical purification
 - conversion processes
 - separation processes

Council of Europe Resolution

Proposed Changes (2)



Proposed New Chemical Listing

➤ Chemical listing split into three parts:

1. **List 1A:** substances evaluated and approved by SCF/EFSA (SCF list 0-4) incl. substances listed in Annex I Table 1 of the Commission Regulation (EU) No 10/2011 on plastic materials intended to come into contact with food as amended (Union list of authorized substances)
2. **List 1B:** substances evaluated and approved by national food safety authorities of EU member states or any other competent authority (e.g. FDA, BfR) and GRAS (generally recognized as safe) substances
3. **List 2:** substances used and well established in the production of resins defined as “food grade” products, but have not yet been specifically evaluated according to EFSA or by other national criteria

Council of Europe Resolution Proposed Changes (3)



Proposed New Compliance Verification:

1. The identity and address of the manufacturer or business placing the ion exchange resins and adsorbents on the market.
2. The identification of the synthetic ion exchange resins and adsorbents.
3. The date of the declaration.
4. Confirmation that the ion exchange resins and adsorbents meet relevant requirements laid down in the Regulation (EC) No 1935/2004.
5. Confirmation that the ion exchange resins and adsorbents meet the requirements of the Council of Europe Resolution 2004/3 (will get new number) and the Technical Documents 1,2,3 (see notes).
6. Compliance that the place of manufacture has and its production are covered by an internationally validated and certified Quality Assurance System.
7. Compliance to the Commission Regulation (EC) No 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food.

Council of Europe Resolution Proposed Changes (4)



Proposed End User Instructions:

- Outlines the areas the end user should familiarise themselves with, and consult with the resin manufacturer before taking delivery of resins for use in food stuff production:
 - The importance of packaging.
 - Minimising on site storage prior to use/shelf life.
 - Correct storage conditions.
 - Inspection/cleanliness of IEX vessels before loading.
 - Correct loading / commissioning procedure.
 - Pretreatment before placing in service.
 - Operating with defined manufacturers guidelines (E.g.: pressure drop, flow rates, operating temperatures and maximum temperature changes etc.)
 - Regenerant quality (where applicable).
 - Thorough testing of initial quality of product produced (approved).

Council of Europe Resolution

Testing (no changes proposed):

- AFNOR method T 90-601:
 - to measure TOC release to prescribed, well defined levels
 - three different simulants to be used:
 1. High quality demineralised water (fully defined in terms of conductivity and TOC content)
 2. Ethanol (15%) for testing alcoholic food stuffs with an alcohol content up to 15%.
 3. Acetic acid (3%) for testing acidic food stuffs with a pH below 4.5.

Potable Water



2012 at SCI Conference reported:

- NO EU wide Regulation / Directive exists for products used in drinking water applications.
- European Acceptance Scheme (EAS 1999 – 2004) abandoned.
- 4 member state (MS) initiative: Jan 2011 declaration of intent. Review of national systems, development of common principles leading to mutual recognition.
 - Construction products in scope
 - IER excluded from first mandate.
- Country specific certifications required: France, Germany, United Kingdom, The Netherlands, and many more....

Potable Water

Today:

- Still a lack of harmonised approach to the regulatory requirements covering ion exchange resins and adsorbents in municipal water treatment
- Although ion exchange resins are not specifically excluded from the intent of the 4MS group, ion exchange resins due to their special properties require a separate approach.
This has not been in scope of the workgroup.

Potable Water

Principle Requirement in Europe (not ion exchange specific):

- Article 10 of the EU Drinking Water Directive 98/83/EC:
 - defines how products used in potable water treatment should not detrimentally effect or interfere with the water quality produced
 - Directive => Member state compliance is national responsibility
=> countries have introduced their own standards

Article 10




Quality assurance of treatment, equipment and materials

Member States shall take all measures necessary to ensure that no substances or materials for new installations used in the preparation or distribution of water intended for human consumption or impurities associated with such substances or materials for new installations remain in water intended for human consumption in concentrations higher than is necessary for the purpose of their use and do not, either directly or indirectly, reduce the protection of human health provided for in this Directive; the interpretative document and technical specifications pursuant to Article 3 and Article 4 (1) of Council Directive 89/106/EEC of 21 December 1988 on the approximation of laws, regulations and administrative provisions of the Member States relating to construction products ⁽¹⁾ shall respect the requirements of this Directive.

Potable Water



Main National Certification Schemes

- UK WRAS (Water Regulatory Advice Scheme) & DWI (Drinking Water Inspectorate)

- Germany DIN 19636-100
- France ACS (Attestation de Conformite Sanitaire) in accordance with the regulations issued by French Ministry of Health and ANSES (French agency for Food, Environmental and Occupational Health and Safety)


Potable Water



Main National Certification Schemes

- Netherlands The Dutch Drinking Water Regulation
- Italy Italian Ministerial Decree No. 174
- Switzerland SVGW - Schweizerischer Verein des Gas und Wasserfaches



.... and many other European countries have their own requirements and approval schemes, e.g. Denmark, Poland, Austria

Potable Water

Our concerns:

- more difficult sources have to be considered as the demand for water grows, thus the applications where resins will be considered and used will continue to grow.
- e.g. the following list of applications, where resins are either in wide spread use or under evaluation for municipal water treatment.
- this growth is welcomed and while some of the contamination/applications may be site or country specific, it is not practical, or cost effective to have the current situation whereby products have to be approved by so many bodies across Europe.

Potable Water



List of Municipal Potable Water Applications:

<u>Application</u>	<u>Resin Type</u>
Hardness Reduction	Strong Acid Cation / Weak Acid Cation
Nitrate Removal	Strong Base Anion
Boron Removal	Chelating Resin
Arsenic Removal	Strong Base / Modified Anion Resin
Chromate (Hexavalent) Removal	Weak and Strong Base Anion
Pesticide Removal	Strong Base Anion / Adsorbent Polymers
TOC/NOM Reduction	Weak Base / Strong Base Anion / Adsorbents
Colour Removal	Weak Base / Strong Base Anion / Adsorbents
Perchlorate Removal	Strong Base Anion
Radium Removal	Strong Acid Cation
Fluoride Removal	Modified Strong Acid Cation
Bromide Removal	Strong Base Anion
Uranium Removal	Weak Base / Strong Base Anion
Heavy Metal, including lead removal	Weak Acid Cation
Total Dissolved Solids Reduction	Weak Acid Cation / Strong Acid Cation / Weak Base Anion / Strong Base Anion

Conclusion



For further information or questions you may get in contact with the SOIA group.

SOIA recently launched a web site:

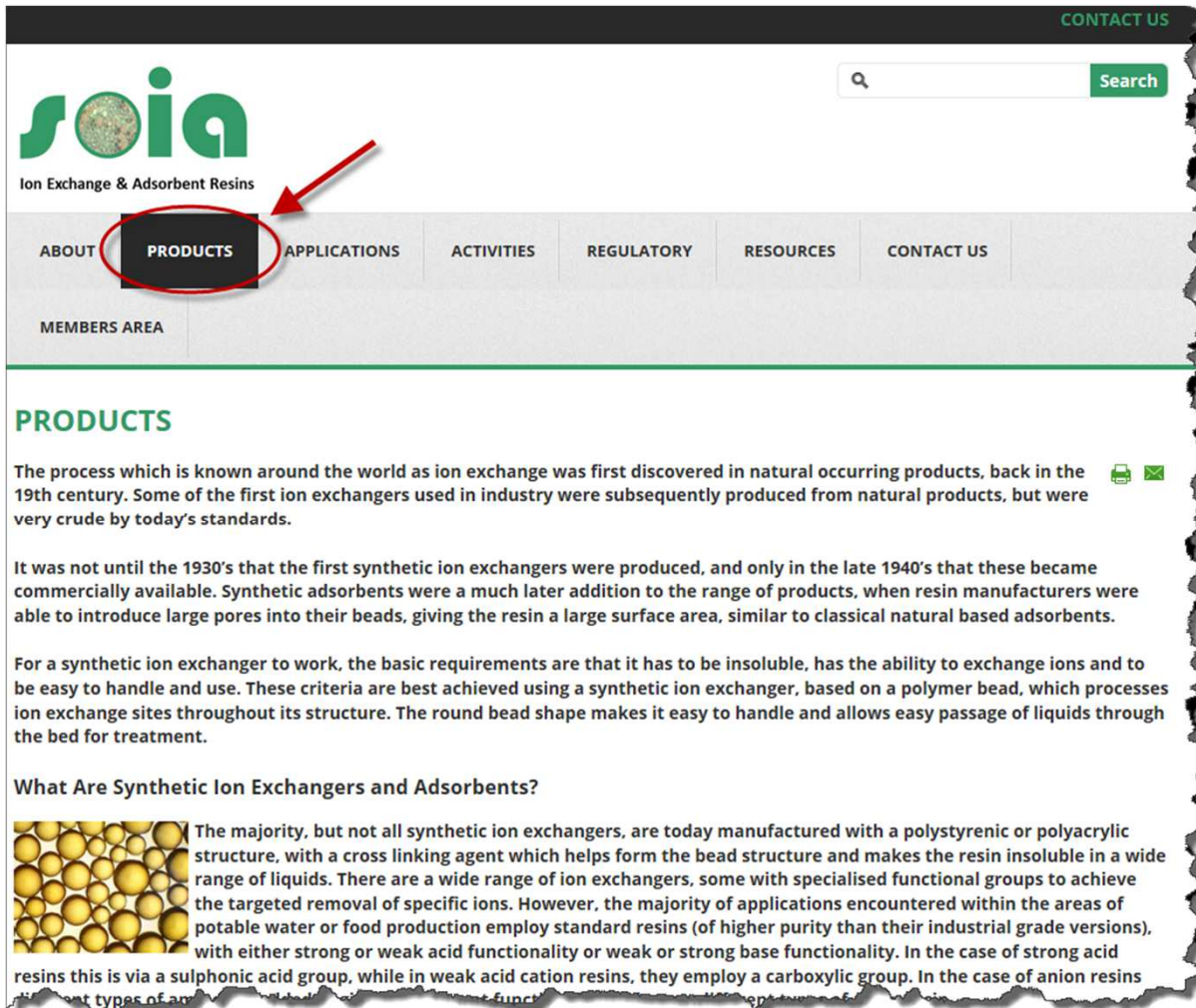
<http://soia.cefic.org/index.php/about>

Conclusion – SOIA Website



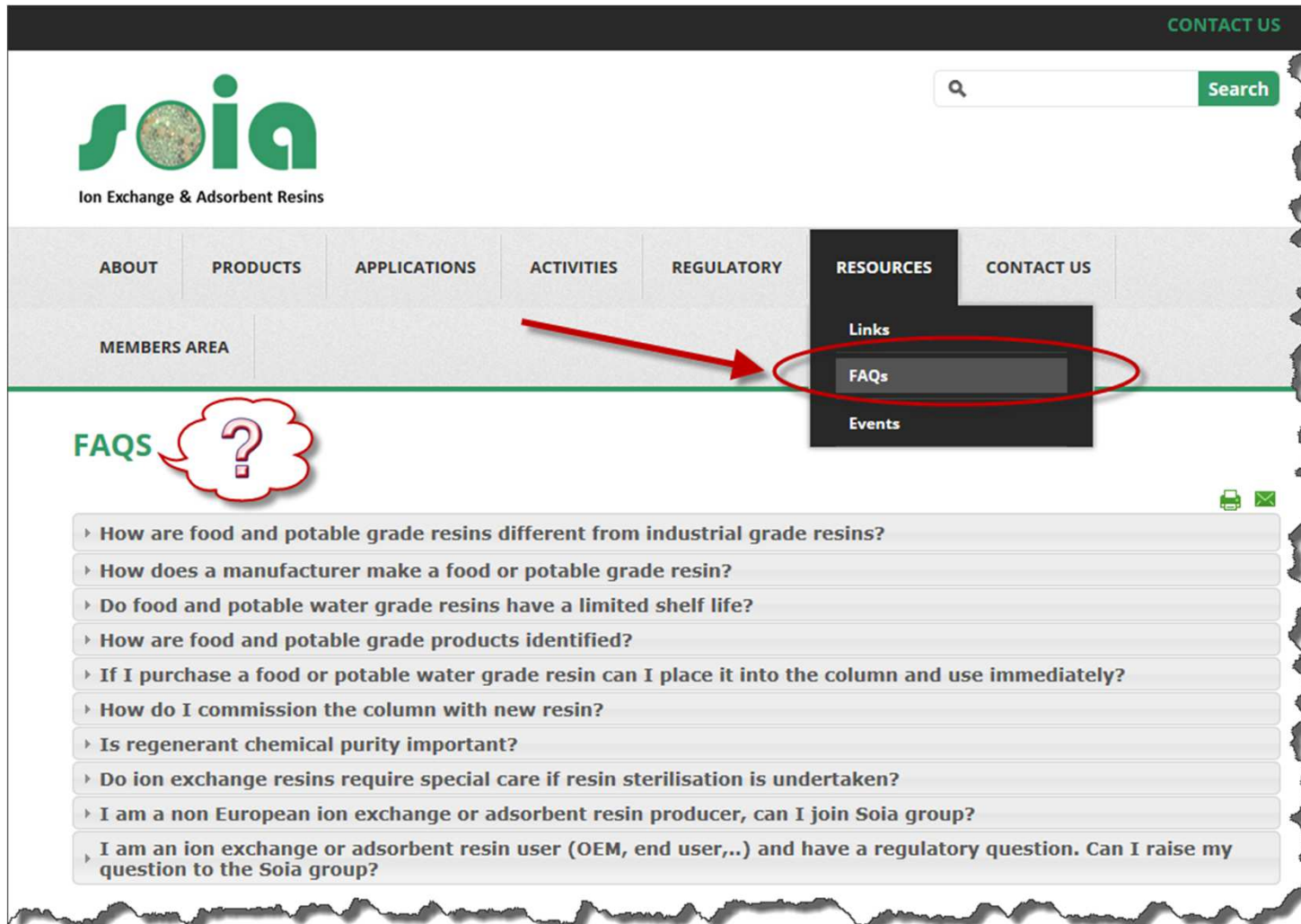
A screenshot of the SOIA website with a torn-edge effect. The top navigation bar includes "CONTACT US" and a search box. The main menu has "ABOUT" (highlighted), "PRODUCTS", "APPLICATIONS", "ACTIVITIES", "REGULATORY", "RESOURCES", and "CONTACT US". A "MEMBERS AREA" link is also present. The "ABOUT SOIA" section features a large image of an industrial facility with long, parallel water channels under a blue sky. To the right of the image, the text reads: "SOIA (Synthetic Organic Ion Exchangers and Adsorbents) is a sector group of Cefic (the European Chemical Industry Council) and this group represents the five leading European manufacturers of ion exchange resins and adsorbents: Dow, Finex, Lanxess, Purolite and Resindion, who supply resins worldwide under leading brand names." Below this text is a link: "Contact SOIA Secretariat." There are also small icons for a printer and a checkmark.

Conclusion – SOIA Website



The screenshot shows the SOIA website interface. At the top right is a 'CONTACT US' link. Below it is the SOIA logo and tagline 'Ion Exchange & Adsorbent Resins'. A search bar with a magnifying glass icon and a 'Search' button is located to the right of the logo. A horizontal navigation menu contains the following items: ABOUT, PRODUCTS (highlighted with a red circle and a red arrow pointing to it), APPLICATIONS, ACTIVITIES, REGULATORY, RESOURCES, and CONTACT US. Below the navigation menu is a 'MEMBERS AREA' link. The main content area is titled 'PRODUCTS' in green. The text below the title describes the history of ion exchange, starting from natural occurring products in the 19th century to synthetic ion exchangers in the 1930s and 1940s. It explains the requirements for a synthetic ion exchanger to work, such as being insoluble and having the ability to exchange ions. A section titled 'What Are Synthetic Ion Exchangers and Adsorbents?' follows, accompanied by an image of yellow spherical resin beads. The text explains that most synthetic ion exchangers are made with a polystyrenic or polyacrylic structure and cross-linking agents, and are used for targeted removal of specific ions in applications like potable water and food production.

Conclusion – SOIA Website



The screenshot shows the SOIA website interface. At the top right, there is a 'CONTACT US' link. Below the logo, there is a search bar with a magnifying glass icon and a 'Search' button. The main navigation menu includes: ABOUT, PRODUCTS, APPLICATIONS, ACTIVITIES, REGULATORY, RESOURCES, CONTACT US, and MEMBERS AREA. The 'RESOURCES' dropdown menu is open, showing 'Links', 'FAQs', and 'Events'. A red arrow points to the 'FAQs' option, which is also circled in red. Below the navigation, the 'FAQS' section is displayed with a question mark icon. It contains a list of ten frequently asked questions, each with a right-pointing arrow icon. At the top right of the FAQ list, there are icons for printing and closing the list.

CONTACT US

soia
Ion Exchange & Adsorbent Resins

Search

ABOUT PRODUCTS APPLICATIONS ACTIVITIES REGULATORY RESOURCES CONTACT US MEMBERS AREA

Links
FAQs
Events

FAQS ?

- ▶ How are food and potable grade resins different from industrial grade resins?
- ▶ How does a manufacturer make a food or potable grade resin?
- ▶ Do food and potable water grade resins have a limited shelf life?
- ▶ How are food and potable grade products identified?
- ▶ If I purchase a food or potable water grade resin can I place it into the column and use immediately?
- ▶ How do I commission the column with new resin?
- ▶ Is regenerant chemical purity important?
- ▶ Do ion exchange resins require special care if resin sterilisation is undertaken?
- ▶ I am a non European ion exchange or adsorbent resin producer, can I join Soia group?
- ▶ I am an ion exchange or adsorbent resin user (OEM, end user,...) and have a regulatory question. Can I raise my question to the Soia group?

Conclusion – SOIA Website



➤ contact the group on general questions/observations:



CONTACT US

Address
Cefic aisbl Av. E. Van.
Nieuwenuyse,4 Brussels
1160

Contact No
+32 (0)2 6767248

Mail Us
can@cefic.be

Download information as:
vCard

Contact Form


Send an Email. All fields with an asterisk (*) are required.

Name *

Email *

Subject *

Message *



Thank You for Your Time!



Cefic – Belgium:

Caroline Andersson

Dow – Germany:

Marie-Rose Diebold

Finex Oy – Finland:

Niina Lehtonen

Lanxess – Germany:

Katrin Wieland

Purolite – UK:

Brian Windsor

Resindion Srl – Italy:

Valentina Scilletta

