

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

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ABSTRACT

Synthetic resins are often used in many applications, mainly to purify or remove contamination, or control undesirable levels of ions etc. Two of the most sensitive applications are in food contact, and drinking water production (including removal of toxins). In such applications they need to perform without making any detrimental changes or additions to the material processed. To achieve this specially manufactured and subsequently cleaner resins, than the widely used traditional “industrial grade” resins, must be used by end users.

Four years ago, the SOIA group (made up of the leading synthetic ion exchange resin manufacturers within Europe) presented a paper to this conference on the regulatory requirements for synthetic ion exchangers and adsorbents used in the production of food stuffs and potable water¹. In particular, we explained the background to the use of ion exchange in food/potable water applications and some of the general regulatory requirements. We concentrated on two areas, mainly on the standing of the council of Europe Resolution covering food grade resins and regulatory requirements in Europe for resins used in potable water production.

This latest discussion paper provides an update on developments in this field, with regard to regulatory matters and the continued work of the SOIA group.

1. INTRODUCTION

This paper is aimed at assisting end users, researchers, and engineering companies, by providing them with a greater detailed understanding of the proposed changes to the current regulatory requirements, when using synthetic ion exchange and adsorbents resins (hereafter referred to as “resins”), in the production of food or potable water in Europe. We have also included for general interest a table showing the areas where synthetic ion exchange resins are currently being used in potable water production or are being investigated as the potential solutions to specific contamination issues in potable water supplies.

1.1 Cefic

First we must remind you about the Cefic organisation and how it operates. Cefic, the European Chemical Industry Council, is a Brussels based association representing approximately 30,000 large, medium and small chemical companies in Europe. As the voice of the European chemical industry, Cefic is a committed partner to EU policymakers, facilitating dialogue with industry on various important technical or regulatory issues to be tackled on a cross industry basis. There are approximately 100 sector groups within Cefic, one of which is the **S**ynthetic **O**rganic **I**on Exchangers and **A**dsorbents Group (SOIA). This group is primarily concerned with regulations covering resins used in the production of food and potable water applications in Europe. The group now brings together the five leading European suppliers, with the addition of Finex from Finland since our last paper at Cambridge (Dow, Finex, Lanxess, Purolite and Resindion), all of which have European production sites and supply a wide range of products to these markets and strongly support pan European regulations.

Each company is represented in the group and Cefic convenes group meetings at least twice per year to discuss regulatory topics relevant to supplying these resins in Europe. The meetings and all communications related to these issues are organised, controlled, reported and monitored by Cefic. Competition law is fully respected and it is strictly forbidden to discuss commercial matters.

In effect, the primary activity of the group is to represent this special market sector, monitoring updates on the European requirements for resins in both food processing and drinking water production.

To date the group's prime activity has been involved with:

- Council of Europe Resolution COE ResAP(2004)3.
- National Legislation monitoring in food and potable water production.
- EU Legislation monitoring (REACH, Plastics Implementation Measure (PIM), etc.).
- Other regulatory topics.

1.2 Market and Trends in the Food Grade/Potable Water Market

The industry is pleased to report that the market for food grade and potable grade resins continues to grow, both with regard to the volume of resin installed and new applications for synthetic resins. The awareness of end users to use fully regulated products in accordance with specific international standards is, we are pleased to report, growing. However, we are still seeing the use of some USA standards in Europe such as clients requesting "FDA resins" and other USA standards when dealing with European based companies/applications, suggesting we still have a long way to go in educating end users on the current European regulations.

2. FOOD GRADE RESINS – COUNCIL OF EUROPE RESOLUTION UPDATE (Outlining proposed changes to the Resolution)

At the last SCI conference, we reported that the Belgian authorities had taken on the task of updating this resolution, with a view to possibly taking this into Belgian law at a later date. We had hoped today, to present information on the newly published resolution, but as is often the case in Europe it takes some time for every state to agree and this is now not expected to be approved before 2017. Since our last paper a significant amount of work has been undertaken by the SOIA group in presenting our proposals for the update of this Council of Europe Resolution. In this paper we are presenting the views we have submitted to the Belgian authorities to make this document more user friendly, informative and clearer to those who are using resins in food stuff production. As the five leading manufacturers, we are dealing daily with end user queries on food grade resin use and the regulatory requirements. We therefore believe we are in a good position to help the authorities to formulate a more robust and clear resolution. As such we expect much of what we have detailed below, in this discussion paper, to appear in the new resolution.

2.1 Council of Europe Resolution – Proposed Extension Field of Application (Pharmaceutical Production)

One of the changes proposed by the Belgian authorities is that the field of application for the resolution should be extended. It is proposed that the resolution will in future, not only cover the synthetic resins and adsorbents used in production of food stuffs, but will also apply to the bioprocessing field and will cover these products when used in the manufacturing process of pharmaceutical products (e.g. pharmaceutical purification, conversion or separation processes). The SOIA group support this proposal as this has always been a grey area that requires a more robust regulatory document offering clear guidance to both suppliers and end users.

2.2 Council of Europe Resolution – Proposed New Chemical Listing

The present resolution defined the chemicals used in synthetic resin production in two lists. This listing was somewhat confusing to those not directly involved, as the description applied to these lists could be open to different interpretation.

The complete listing covers the monomers, starting substances and additives used in the manufacturing of synthetic resins.

The new SOIA proposal is that the chemical listing is now split into three parts, Lists 1A, 1B and 2. This new classification proposes the chemicals used by the five manufacturers are covered by the evaluations proposed below:

List 1A:

These substances have been evaluated and approved by SCF/EFSA (SCF list 0-4)

including substances listed in Annex I Table 1 of the Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials intended to come into contact with food as amended (Union list of authorized substances)

List 1B:

These substances have been evaluated and approved by national food safety authorities of EU member states or any other competent authorities (e.g. FDA, BfR) and GRAS (Generally Recognized As Safe) substances as listed on the US FDA GRAS Substances (SCOGS) Database.

List 2:

These substances are 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.

In addition, proposed criteria is outlined for the approval of chemicals listed in List 2 if required.

It should be remembered that when the initial resolution was formulated in the early 1990’s, all the resin manufacturers who were members of the SOIA group at that time, submitted their “food grade” resins and other products to third party independent laboratories for testing to establish compliance with the regulatory requirements of the resolution. This means we have a detailed understanding of the requirements and production techniques needed to manufacture compliant products.

2.3 Council of Europe Resolution – Proposed New Compliance Verification

Compliance of the products supplied in accordance with this resolution has always been available from the leading European manufacturers under their in house quality systems. The new proposal defines exactly the certification from the five compliant resin manufacturers in Europe should provide. This certification should be requested by all end users when supplied with products compliant with this regulation.

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.

2.4 Council of Europe Resolution –Testing

In our previous paper we defined the test procedure used to show compliance with the Resolution based on the AFNOR method T 90-601. This is used to measure TOC release to prescribed, well defined levels. We would remind readers that to ensure different types of food stuffs are covered by the test, three different stimulants can 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.

2.5 Council of Europe Resolution – Proposed End User Instructions

The present resolution concentrated mainly on the regulatory aspects of resin production and the products meeting defined criteria. It is clear however, that some clients on receipt of such products do not always understand the importance of how they should store or handle the products when reaching site. In particular they are not ensuring that loading/commissioning and pretreatment of the resin beds is carried out correctly and how important this is in achieving compliant performance.

The new document will outline 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.

These include:

- 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 (For example: pressure drop, flow rates, operating temperatures and maximum temperature changes etc.)
- Regenerant quality (where applicable).
- Thorough testing of initial quality of product produced (approved).

Experience tells us many end users do not fully appreciate these factors, which will affect the performance and in some cases the purity of our products in service. It is important to remind end users that resins are synthetic chemicals which can be damaged by oxidising agents, and

can undergo attrition certain conditions, if subjected to osmotic shock or abrasion leading to attrition products and hence chemical and physical breakdown and possible downstream contamination. Sterilisation procedures by end users should therefore bear in mind the potential damage that can be caused. Oxidising agents attack the resin matrix causing the loss of ion exchange sites and in some resins they will also attack the active groups.

The importance of filtration/resin traps downstream of the unit containing the resin is critical if serious situations of contamination by attrition products are to be avoided. In fact, many plants do not have robust distribution/collection systems, which are not inspected on a regular basis. All SOIA members know of clients in the food industry where internal collection systems have failed within the columns holding our resins, leading to release of resin and serious downstream contamination of product with whole or broken resin beads! This has resulted in lost production time and sometimes valuable product being lost and therefore considerable cost to the end user, which could so easily be avoided with the correct post filtration.

3.0 POTABLE WATER

As defined in our previous paper the SOIA group continues to find the situation in the potable water market frustrating with a lack of harmonised approach to the regulatory requirements covering ion exchange resins and adsorbents in municipal water treatment.

Since the last conference we have been trying to get the Joint Management Committee of the 4MS Group, which is looking into harmonisation of the regulations covering potable water products, to consider adding resins to their agenda for review. So far we have failed, possibly because resins have, up to know, been considered intrinsically “safe”.

The principle regulatory requirement in Europe, which is not ion exchange specific is Article 10 of the Drinking Water Directive which defines in broad terms how products used in potable water treatment should not detrimentally effect or interfere with the water quality produced. To meet this requirement countries have introduced their own standards which have to be met. The following list gives an indication of the main regulations covering some of the leading countries in Europe we encounter in having our products formally approved:

UK	WRAS (Water Regulatory Advice Scheme) & DWI (Drinking Water Inspectorate) approvals (depending on the application)
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)
Netherlands	The Dutch Drinking Water Regulation

Italy Italian Ministerial Decree No. 174

Switzerland SVGW (Schweizerische Verein des Gas und Wasserfaches)

Many other European countries (Denmark, Poland, Austria, etc.) either have their own requirements or will recognise approvals of products under the above schemes.

An excellent report on the requirement for a practical harmonisation policy in Europe, to meet Article 10 of the Drinking Water Directive and the potable water market needs has been produced by a Dutch consultancy company, Panteia Research to Progress².

Our concerns are that as the demand for water grows and more difficult sources have to be considered, the applications where resins will be considered and used will continue to grow. For example, below we have listed 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.

We hope this listing may be of interest to those involved in production of potable water on a municipal or commercial scale.

3.1 List of Municipal Potable Water Applications (in common use or under evaluation)

Table 3.1.1 An outline list of potable water applications including general and ion specific (selective) resins

<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
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4.0 CONCLUSION AND CEFIC SOIA WEB SITE

4.1 Conclusion (Launch of CEFIC SOIA web site)

We trust that this paper outlines the progress made in some areas over the last four years and the frustrations which the resin industry still feels on the lack of progress in other areas such as potable water harmonisation.

To help the end users, researchers, and engineering companies, who must find this area difficult to monitor, but are working in the field where resins are used in the purification or treatment of food stuffs and potable water, SOIA have now launched a web site. While this is at a very early stage we are trying to ensure this site is up to date on general information covering these two important topics. It also provides information of how the SOIA group can be contacted and includes a “frequently asked questions” section, which we hope to expand. We believe that those interested in these topics will obtain helpful information and many of their questions answered. It is our intention to continue to build up the information and keep the web site valid and updated at least twice per year on current news within these market sectors.

The web site address is

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

REFERENCES

¹ **Marie-Rose Diebold and Peter Van Herwijnen** (*Dow Water & Process Solutions - Germany*), **Caroline Andersson** (*Cefic-Belgium*), **Katrin Wieland and Gritt Hamsen** (*Lanxess-Germany*), **Valentina Scilletta and Enrico Mercalli** (*Resindion Srl - Italy*), **Brian Windsor** (*Purolite International – UK*)

European regulatory requirements for Synthetic Organic Ion Exchange Resins and Adsorbents used in food processing and potable water production. SCI IEX2012 Conference Cambridge.

² **Panteia (Research to Progress)**

Report on the Economic Effects of article 10 of the Drinking Water Directive