

# CESIO

## news



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EUROPEAN COMMITTEE OF SURFACTANTS AND THEIR ORGANIC INTERMEDIATES

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## SPECIAL ISSUE

### CESIO contribution to the Public Internet Consultation of the EU Commission on the New Chemicals Legislation - REACH<sup>1</sup>

#### Introduction

On May 15, the EU Commission presented its draft of the "New Chemicals Legislation - REACH" in the Internet asking for comments.

Whilst CESIO fully supports and agrees with the objectives of the proposed REACH legislation it is concerned with the massive amount of resources, financial as well as manpower, needed to implement the proposals in the given time and believes that this alone makes the proposals in this Consultation Document unworkable within the suggested time frame.

CEFIC as well as other associations have submitted detailed documentations. CESIO supports the CEFIC response without reservation, but believes to have additional experience and specific knowledge in certain areas which should be considered during the further evaluation of the legislation. These are presented below.

<sup>1</sup> with some minor editorial modifications

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## The surfactant industry in Europe

CESIO represents the surfactant industry in Western Europe. This industry and the markets it serves are extremely complex and highly fragmented:

- A large number of surfactant producers. In total the number is estimated to be 100\* (about 49 members in CESIO)
- The numerous product types (estimated to be 3 400\*)
- A wide range of end-use markets, each with many customers formulating about 100,000\* products in total
- Use in a number of technical applications for production of other products/articles
- Sales of surfactants and intermediates between producers of different sizes and production capabilities.

The surfactant producers not only sell to end users, but also sell intermediates as well as surfactants to each other. This business structure reflects many operational characteristics like the availability of raw materials, production capabilities, and optimisation of transportation costs.

## "Speciality" and "commodity" surfactants

Many surfactant producers have in their portfolio low volume "speciality" and large volume "commodity" surfactants. The latter provide a base load of business to support large capital investments for plant equipment and facilities, while the former provide a diverse product line and can open access to specialised applications where higher percentage margins can generally be obtained. This combination also provides significant opportunities for new business, and some protection from the adverse effects of cyclic economic developments that characterize most commodities in the chemical industry.

As surfactants can have highly specific performance characteristics in their applications, many are purely sold on the basis of performance. Therefore, many companies (especially small and medium sized enterprises) (SME's)

have concentrated on serving the market with tailor-made surfactants for specific technical applications, where technical as well as environmental performance are the main purchasing arguments. The volumes of those tailor-made specialties can be low, as the individual processes and applications for which they are used vary considerably. Typical technical applications with a large number of low volume speciality surfactants are found in the textile- and leather auxiliaries industry, agrochemical industry, metal and mining chemical industry as well as the plastic and lubricants industry.

Especially for the SME surfactant producers, there is a strong need to be very flexible in developing specialty surfactants and offering tailor-made solutions for highly sophisticated uses. Already, the increased costs of complying with chemical and environmental regulations have contributed to a continuing consolidation of the surfactant industry.

## Impact of the legislation on "speciality" surfactants

Over the last 20 years highly specialized performance chemicals have been developed to replace older less efficient "standard" products in a number of specific technical applications. These new products have a high technical as well as optimized environmental performance. However, since they are very specialized the volumes are relatively small and as a consequence the ability to cover high costs for registration is limited. Thus we expect that about 50 % of the individual surfactants will disappear from the market when all surfactants have to follow the REACH procedure. Niche applications which are served mainly by SME's will be most affected.

As a consequence, REACH will lead to a consolidation of the product portfolios of companies where many of the small volume highly specialized products will disappear and be replaced with older "standard working-horse" products, which are less efficient but more versatile in use and thus higher volume. Also export outside of EU of these high performing niche products will not be possible.

\* derived from published data e.g. Surfactants Europe, published by the Royal Society of Chemistry, UK

This will mean a step back both in technical development as well as the environmental optimisation of processes not only within the surfactant industry but in particular within the downstream user industries.

The revenue from many lower volume speciality substances will not support the development of the required amount of data and thus many substances developed for specific roles will disappear from the market and this will have a negative impact on European industry as a whole.

## Chemical safety assessment

The members of CESIO are surfactant manufacturers. They are committed to assess the potential risks associated with their products when manufactured and placed on the market. Priority is given to areas of particular concern.

The procedure presented in the Consultation Document requires a full risk assessment for :

- each end point, regardless of its final relevance and
- each intended use (90 % of the actual uses to be covered)

In preparations this has to be carried out for every ingredient regardless of the amount.

The main industries where surfactants are used are :

- detergent industry
- paper mills/paper industry
- mining/metal industries
- fertilizer
- agrochemicals
- paints
- polymers
- textile/leather
- lubricants
- fuel additives
- oil field chemicals

In each of these industries, several different applications have to be considered. Although the surfactant manufacturers are aware of the major uses - it is extremely uncertain if 90% of the real uses of each individual surfactant, in particular low volume uses, are known to them. Furthermore, the downstream user may deem certain uses as proprietary. Therefore, it cannot be assumed that downstream users will be willing to share detailed information on certain uses. However, it is not realistic that downstream user will be able to carry out the required risk assessment as needed.

CESIO member companies will have to develop several thousands of Chemical Safety Reports (CSR's). It will be impossible to generate all these documents in the 18 month period after this regulation comes into force. Submission of CSR's to customers should be aligned with the registration process.

CESIO believes that the proposed procedure to carry out CSR's is much more demanding than necessary. CESIO supports the initiative of CEFIC and ECETOC to develop a simplified procedure.

The statement above does not refer to what formulators and other downstream users have to carry out. It seems highly unlikely that these parts of the supply chain will be able to comply with the proposed system. Again, CSR's should be made available to the customers according to the time schedule of registration.

## Polymers

CESIO supports the CEFIC position that polymers should be exempted completely from the registration process.

Based on volume alone, about 50 % of the surfactants on the market meet the definition of polymers. When the number of surfactant products (3400, see Introduction) is considered, the ratio of polymers to non-polymers increases dramatically, to about 5:1. The reason is the increased opportunity to tailor the properties of polymers to customer requirements by changing the type of monomers, the monomer composition, the sequence

of monomers, the molecular weight, the molecular distribution of components etc.. Because of the wide variation in composition of the products no reasonable procedure is available to address polymers in the REACH system in an appropriate and effective way. Current legislation views polymers as "existing polymers" when the monomers are "existing chemicals". There is no need to depart from this concept.

Despite the general concerns given above, CESIO would like to make some more specific comments addressing the workability of the criteria of Point 16 of the Consultation Document for polymeric surfactants. Most of the nonionic surfactants and some of the other types are polymers with a molecular weight  $M_n < 10.000$  Dalton. In fact, the vast majority of these surfactants have a molecular weight  $M_n < 1.000$  Dalton. Many of them are classified as dangerous in accordance with Directive 67/548/EEC.

Point 16, 2.(a) says that polymers like surfactants as specified above shall be deemed to be preparations and (b) that components with toxicological and/or ecotoxicological significant reactive functional groups shall be deemed to be substances. Since every homologue of a surfactant polymer bears a reactive functional group an extremely high number of new chemical individuals which until now have never been isolated and for which no data are available would have to be identified, investigated and registered .

According to the existing legislation, polymers are substances as a whole. Classification of polymers as dangerous in accordance with Directive 67/548/EEC is well established and there is no indication that the procedure needs amendment. Assuming that it was not intended to create uncountable new chemicals which have to be registered it must be questioned in general if the assessment of individual homologues in polymer mixtures is necessary and/or proportionate in respect to the expected gain of knowledge.

As a conclusion, CESIO believes that polymers should be exempted from REACH and the classification procedure of polymers must not be changed.

## Data requirements

The proposed system is hazard based and the amount of toxicity and ecotoxicity data required are triggered by volumes only. However the revenues from many smaller volume ( $< 100$  tons/y) specialty surfactants will not support the development of the required amount of data.

The system should be switched to a risk based approach where the first step should be to prioritise chemicals on the basis of exposure. An approach using the newly developed ECETOC targeted risk assessment should be considered. This method confers the considerable benefit that it will considerably reduce the animal testing required when compared with the proposed REACH system.

## Consortia Formation

Experience from ICCA initiative clearly indicates that forming an effective consortium takes considerable resource and time (this is documented in the Independent Review of Certain Processes in the HPV Chemicals Programme, RPA February 2003). This has also been the case for industry's own voluntary initiative – the HERA project in which the European surfactants industry has been an active participant.

In respect of fulfilling the proposed requirements of this consultation document – the issues of consortia formation will be exacerbated by

- considerable increase in the number of consortia due to the number of chemicals being addressed
- increased numbers of participating companies
- increased data flow
- increased administration

This will represent a considerable challenge to companies, especially the SME's who produce a number of speciality surfactants, but will not have the considerable resource required to participate in consortia.

An example of where the benefits of consortia formation (e.g. cost sharing, for example where additional testing is required) have been outweighed by the considerable costs associated with the creation of consortia, management of data without sacrificing confidential information, participation in consortia etc. is manifest in limited number of consortia which have been established in the context of the EU Biocidal Products Directive.

The issues around consortia formation need to be considered further in the development of this regulation – allowing for greater flexibility and more realistic timing.

## Data Sharing

Data required for the REACH process will include production volumes, compositional data, details of special applications, quantities used in the various applications, quantities used in different countries etc.. All this information may need to be disclosed when consortia are formed and/or risk assessments are prepared. Unless an agreed process can be developed to maintain confidentiality, companies will have to assess what is more favourable to them: disclosure and co-operation in consortia or non-disclosure protecting their confidential business information. In many cases, the latter will be preferable leading to reduced involvement in consortia.

## Proprietary Rights

Very often, confidential business information and data protection are confused. The properties of a surfactant (performance, physico-chemical, toxicological, environmental) can be shared, although competitors may use this to their advantage. However, it would be completely unacceptable if a company could use the data of a co-producer for registration without having written approval from the data owner to do so. It is extremely important to establish a scheme protecting those companies which have invested in the creation of product data. Clear rights to ownership of data will be one of the prerequisites for a successful working in consortia. However, experience shows that working in consortia can be very time consuming and not always 100% effective.

## Evaluation procedure

Evaluation of the registration data (standard or priority) is assigned to the Member State (MS) as is the case in the procedure under the current legislation on existing chemicals. Thus no change of today's situation is proposed in the new legislation regarding this key aspect with the risk of different views and agendas driving the decisions. Furthermore, any decision of a MS in a standard evaluation may be challenged by another MS in a priority evaluation, which is not acceptable from a legal certainty point of view.

In the view of CESIO a stronger central agency is needed to ensure a level playing field. The central agency should perform the evaluations and prepare the draft evaluations reports. The role of the MS should be to review and comment on these reports. Re-evaluation should only be initiated by the central agency on the basis of new information.

Evaluation should focus on substances over 100 tonnes and specific substances of concern. Evaluation of all substances below 100 tonnes should be strictly risk related.

The processes of evaluation (and authorisation) should contain provisions for manufacturers and importers that would guarantee the right to be heard, the right to be listened to, the right to actively participate in committees and meetings and the rights of appeal to any decision.

## The Agency

As stated previously, to ensure a level playing field CESIO is in favour of a stronger central agency managing REACH, performing evaluations, preparing and taking decisions after input from MS, industry and other stakeholders. Industry should be involved in the decision-making processes. These processes should contain provisions for manufacturers and importers that would guarantee the right to be heard and the right to actively participate in committees and meetings and the rights of appeal to any decision.

## Future Events

### SETAC Asia/Pacific and the Australasian Society for Ecotoxicology, 28 September 2003, Christchurch, New Zealand

Solutions to Pollution

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### SETAC 24th Annual Meeting in North America, 9-13 November 2003, Austin, Texas, USA

Science Without Borders: Developing Solutions for Global Environmental Challenges

For further information please contact:  
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### EUROFORUM Seminar: Detergents & Cleaning Products 2003 – Biodegradability Biocides, 25-26 November 2003, Paris (France)

- What does the market look for ?
- New Detergents Regulation, Biocidal Products and Dangerous Preparations Directives: actors, procedures and deadlines
- Labelling: obligations and consequences
- Biodegradable surfactants and components: What solutions for your new formulation ?
- Tests of biodegradability and eco-toxicity
- What are the consequences of regulatory evolutions for industry ?

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### The Household, Industrial, Institutional Ingredients Conference (H3I), 3-4 December 2003, Düsseldorf (Germany)

The Household, Industrial, Institutional Ingredients Conference (H3I) will aim to cover all relevant aspects of ingredients used in household and industrial products and institutional cleaners.

During the last decades the development of new raw materials has resulted in products that are time saving, more effective and less aggressive to materials, skin and the environment. Every year we face new products on the market making life much easier. Industrial and Institutional cleaners is one of the most innovative markets.

The emphasis is to produce a programme that contains the most up-to-date and innovative information on the formulation of household, industrial products and institutional cleaners.

For further information, please contact:  
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### 2004 SDA Annual Meeting & Industry Convention, 27-31 January 2004, Boca Raton (Florida)

For further information:  
E-mail: info@cleaning101.com  
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### CED Annual Meeting (Comité Español de la Detergencia Tensioactivos y Afines, 24-26 March 2004, Barcelona (España))

Plenary Lectures, Oral Communications and Posters will be presented on specific scientific-technical topics:

- Raw materials
- Synthesis and Analysis
- New Developments and Applications
- Physico-Chemistry
- Environment
- Legislation
- Markets
- Consumption / Distribution

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### 6th World Surfactants Congress, 20-23 June 2004, Berlin, Germany

CESIO 2004 will stimulate communications between manufacturers and suppliers in order to improve everyone's awareness of where the surfactant industry is going, and what needs to be accomplished in the future. This congress is a great opportunity to learn the latest developments in various areas of the surfactants industry, to discuss key issues with colleagues and to discover opportunities for the future.

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CEFIC, the European Chemical Industry Council, is the Brussels-based organisation representing national chemical federations and chemical companies of Europe. All together, CEFIC represents, directly or indirectly, about 30,000 large, medium and small chemical companies in Europe, which employ about 2 million people and account for more than 30% of world chemicals production.

CESIO (Comité Européen des Agents de Surface et de leurs Intermédiaire Organiques) is the CEFIC sector group representing the European producers of surfactants. The aim of CESIO is to develop and promote surfactants, keeping in mind environment and health.

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