ECHA
EUROPEAN CHEMICALS AGENCY
5 NO
November 2015

Newsletter

REACH 2018: the road ahead

This Newsletter reaches you at a time when our preparations – and I presume yours too – for the 2018 REACH registration deadline are going strong. We here at ECHA have set ourselves the goal to be ready by the end of 2016. Thus, by then, we will be ready to support you in that final sprint!

Support material online

We are publishing material to help for the first two phases of the REACH 2018 Roadmap this year: phase 1 'Know your portfolio' was launched in June and the launch of phase 2 'Find your co-registrants' will take place next week. You can still register for the webinar. http://echa.europa.eu/view-webinar/-/journal_content/56_INSTANCE_DdN5/title/reach-2018-find-your-co-registrants-and-prepare-to-work-together

We will continue creating new support web pages next year as we roll out phases 3 to 6 of the Roadmap. You can find more information about the phases and links to the relevant support material on our REACH 2018 web pages. http://echa.europa.eu/reach-2018

Of course we know that registration is not a linear step-by-step process. The different phases are very interlinked - you move from one phase to another and then back again.

We also understand that not everyone will be following our timetable. You should, nevertheless, be aware that it can take anything between six months to three years to pull together a registration dossier with your co-registrants. Therefore, it is important that you have an overall understanding of the whole 'road ahead' as soon as possible.

New IT tools
Next summer, you will be able to use a 'new generation' of our IT tools: IUCLID for creating dossiers; REACH-IT for submitting them; and Chesar for preparing chemical safety assessments. You will see notable changes to the customer interface and functionalities. The way we support you in their use will also radically change. They will be much more user-friendly than the current tools. We have learnt a lot from company users to understand their practical needs as well as frustrations with the current generation of tools.

If you are a newcomer to REACH, we advise you to wait for the updated tools before you prepare and submit your dossier, to benefit from these developments.

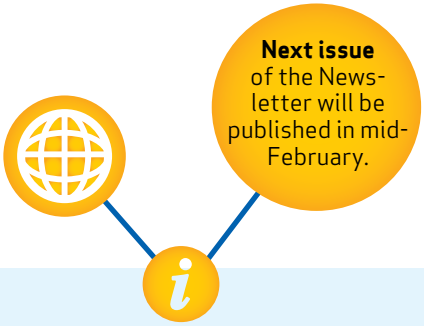
Help us reach the unaware
As subscribers to this Newsletter, you already regularly follow our news. However, many surveys show that a lot of companies are still unaware of their obligations. This applies particularly to downstream users who should be informing registrants about their uses. Our partners from industry, the European Enterprise Network and national helpdesks have come together in a REACH 2018 Communicators' Network that helps us to reach out to the unaware.

We would also appreciate your help. If you find that any of your business partners are unaware of their duties, please guide them to our new "Getting started" web pages aimed at companies who are just getting to know the EU chemicals legislation. Through these pages, you can also access our new publication "Chemical safety in your business – introduction for SMEs". They are both available in 23 languages. Just an idea: you might even consider sharing this link by printing it on your letterheads or invoices. http://echa.europa.eu/support/getting-started

This Newsletter is published exactly 929 days ahead of the registration deadline. Just check: the REACH 2018 web pages provide you with a clock that is continuously ticking towards our goal.

Andreas Herdina
Director of Cooperation

"If you are a newcomer to REACH, we advise you to wait for the updated tools before you prepare and submit your dossier to benefit from these developments."



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New substance infocards - more useful and transparent information on chemicals

INTERVIEW BY HANNA-KAISA TORKKELI

In January 2016, ECHA will change the way in which you will see chemicals data on our website. Information on up to 120 000 chemicals will be structured in three layers: Infocard, Brief Profile and detailed source data.

The most impressive new feature is the **Infocard**, which offers a summary of the key information on a substance in plain English.

"Users will be able to see at a quick glance the key properties of the substance: how it is classified and whether it is hazardous or not. And, if the substance has worrying properties, the Infocard also shows how the substance is being scrutinised by the regulators," says *Ms Christel Musset*, Director of Registration at ECHA.

"It will be very useful, for example, to workers and downstream users as well as citizens interested in chemicals."

BIGGEST IN THE WORLD

ECHA's database is one of the biggest sources of regulatory information on chemicals in the world. It integrates the information from REACH registrations and C&L notifications with substance evaluation and risk management processes, such as harmonised classification and labelling, authorisation and restriction.

For biocides, ECHA publishes information on active substances, biocidal products as well as a list of active substance and product suppliers. Statistics on the export and import of hazardous substances that are regulated under the Prior Informed Consent Regulation (PIC) are also made available.

Ms Musset is open to the idea that in the future ECHA's database would cover even more widely the European legislation affecting chemical substances. Immediate focus is still, however, in improving the usability of the current information.

"Our aim is to make it even better. After the January launch, we will work further on integrating information from all our regulatory processes in the website. For example, the user will be able to see how a certain substance progresses in dossier evaluation."

In 2016-2017, the Agency will be testing different models for delivering data from the portal so that the stakeholders can use the information for their own needs. "Academic researchers might, for example, be interested in utilising the information to build QSAR predictions."

QUALITY OF DATA MORE PROMINENT

As the revamp restructures the information and makes it more transparent, it also makes the discrepancies in the data more visible. This is the case in particular with the different classifications and uses of the substance. "For example, it will be easy to verify whether a substance registered as an intermediate is used for applications that are not in line with the boundaries of an intermediate registration."

Companies are encouraged to keep their dossiers up-to-date with the latest information they have. "Good quality information on the substance increases the trust of the public in the chemical industry."

Christel Musset.

TOWARDS SAFER CHEMICALS

With dissemination, ECHA has first ensured that information from the registration dossiers and the C&L Inventory would be made publicly available. It is now gradually moving towards making best use of this wealth of information in the regulatory processes as well as for the general public.

In the global picture, the launch can be linked to the United Nations' World Summit on Sustainable Development.

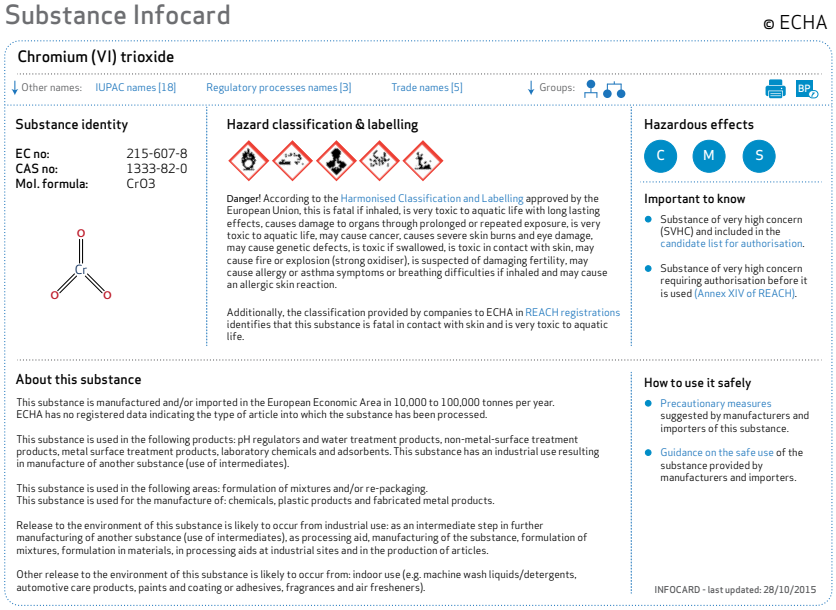
"In 2002, the international community made a commitment to gather information about chemicals and make this information publically available. Our website is a big contribution to that goal from the EU," Ms Musset concludes.

Further information:

Information on chemicals – Watch this space in January 2016!
http://echa.europa.eu/information-on-chemicals

From an info card to detailed source data - ECHA's plans for chemicals communication, Newsletter 1/2014
http://newsletter.echa.europa.eu/home/-/newsletter/entry/1_14_from-an-info-card-to-detailed-source-data

Are you interested in writing about the new Infocard for your own publication? Contact ECHA press: press@echa.europa.eu.



The most impressive new feature of the restructured chemicals database is the Infocard, which offers a summary of the key information on a substance in plain English.

From our stakeholders:

"Eight years after the introduction of REACH, ECHA possesses one of the most extensive databases of European chemicals. Industry and NGOs can benefit from it in different ways – for registration purposes, searching for specific information and so on. Now, the information is even more accessible through the Infocards and Brief Profiles.

Through these, REACH will strengthen its role in giving information on the handling of chemicals in the workplace. Trade unions have always been demanding short and understandable information about the properties of substances. Extended safety data sheets are difficult to understand and not fit for purpose.

The new functionalities of the dissemination portal completely fill the gap on providing meaningful and reliable information on substances. Thus, in practical terms, REACH is contributing to better health and workplace protection. My hope is that the link to the Brief Profile is given a prominent place in the database, so that workers who do not use ECHA's website very often can benefit from this."

Gertraude Lauber,
German trade union
IG Bergbau, Chemie, Energie (IG BCE)

"Following the REACH 'no data, no market' principle, before a chemical is allowed in the market, manufacturers and importers must register it and prove it is safe by submitting information on identification, hazards, volume, exposure scenarios description, recommended risk management measures, etc.

Only once there is a clear picture on the chemicals present in the market - thanks to the information provided by companies - will competent authorities be able to regulate chemicals. This information would also enable citizens to be better informed on the chemicals they are exposed to and to make informed decisions. The registration dossiers are therefore the pillar of REACH.

The EEB welcomes ECHA's new dissemination features since it makes this information more easily accessible to the public, providing clearer, more organised and more concise information about the potential health and environmental risks caused by chemicals.

The new portal is an important step towards closing the knowledge gap on the chemicals present in the EU market."

Tatiana Santos, Senior Policy Officer at the European Environmental Bureau (EEB)

REACH 2018

How to get in contact with your co-registrants

INTERVIEWS BY HANNA-KAISA TORKKELI

Once you know which substances you need to register by the 31 May 2018 deadline, you need to start looking for the other companies that intend to register the same substances as you. You will need to work together to share data and prepare a joint registration. Three companies share their tips on how to find your co-registrants.



Marc Cremers (left), Sigrídur Ingimarsdóttir and Barbara Maresta.

***Barbara Maresta*, Eigenmann and Veronelli:**

The first step is to check which of the substances that you pre-registered you still want to to use in the future, what their import volume or produced tonnage is and their precise substance identity.

The second step is to check whether they have already been registered or not. If the substance has been registered, you have to contact the lead registrant, determine that the substance is in fact the same as yours and then start discussions on the substance information exchange forum (SIEF) agreements.

***Sigrídur Ingimarsdóttir*, Haldor Topsoe:**

If your substance is not yet registered, go to REACH-IT and see who intends to register your substance. You can see all the pre-registrants in the pre-SIEF page of REACH-IT. Contact the other pre-registrants or the SIEF Formation Facilitator (SFF) to get your pre-SIEF active.

***Marc Cremers*, KBM Master Alloys B.V.:**

If no SIEF facilitator exists, send an email to all pre-SIEF members asking for their registration intentions and what work they are prepared to do for the joint registration.

It is very important to find those companies interested in registering, because you can only proceed by yourself if none of the other pre-SIEF members are interested (one substance, one registration principle of REACH).

Ms Maresta:

Small and medium-sized enterprises (SMEs) should not be scared about contacting big companies. It is important to know what your duties and rights are, and what needs to be done to complete all the activities and phases of REACH registration. When you contact the lead registrant, they have to reply to you - it's their responsibility.

SHARING ACTIVITIES WITHIN THE SIEF

Ms Ingimarsdóttir:

Make sure that you know the requirements and have a good understanding of the whole registration path ahead. Get to know the intentions of your co-registrants and what kind of experience and knowledge they have. Have an open dialogue, but also remember to respect competition law. Decide on how you will share the work and cost upfront. You can contact your industry organisations for advice.

Ms Maresta:

Share the activities step-by-step. Make a strategy for your registration. When preparing a dossier in the past for a substance not registered, we worked with a few other companies for nearly two years, comparing our analytical data on the substance and checking the impurities.

We started very early to complete the registration dossier on time. We were not the lead registrant, but we worked very closely with them. We had a common interest to do things on time and in a good manner.

Mr Cremers:

For several of our substances that have not yet been registered, we are working with a consortium that does the work for us, the REACH orphan substances consortium. The consortium is managed by an experienced REACH consultant. Basically, what we do is attend meetings, gather the information from our own company and vote on the choice of technical service provider, for example, the laboratory that will do the analytical testing.

Further information:

REACH 2018 phase 2:
http://echa.europa.eu/reach-2018/find-your-co-registrants

Getting started with EU chemicals legislation:
http://echa.europa.eu/support/getting-started

Chemical safety in your business:
http://echa.europa.eu/documents/10162/21332507/guide_chemical_safety_sme_en.pdf

Terminology – in 23 languages
http://echa-term.echa.europa.eu/

INTERVIEWEES' TOP TIPS FOR SMES:

- Start now. Registration takes time and the longer you wait, the higher the costs will become for laboratories and consultants.
- Make a REACH 2018 inventory as soon as possible. For each substance, determine the manufacture or imported tonnage.
- Get familiar with your legal requirements.
- Be clear on your substance identity. This will ensure that you really are working together with companies registering the same substance as you.
- Get to know the IT tools IUCLID, REACH-IT and Chesar.
- Be clear on your uses and make sure that the registration covers your use.

EIGENMANN AND VERONELLI SPA

Eigenmann and Veronelli SpA is a distributor and producer of fine, specialty and performance chemicals. Serving its main markets in Italy, Spain, Portugal, Russia and Turkey, Eigenmann and Veronelli offers chemical products and services to a wide variety of industry's needs.
http://www.eigver.it/evenu/default.aspx

HALDOR TOPSOE

Haldor Topsoe is a Danish catalysis company founded in 1940. It is a world leader in catalysis and surface science. The company has over 2 700 employees all over the world of which 2 100 work in Denmark.
http://www.topsoe.com/

KBM MASTER ALLOYS B.V.

KBM Master Alloys B.V. is a producer of master alloys. Production takes place in two metallurgical plants in the Netherlands.
http://www.kbmaffilips.com

Want to know about...socio-economic analysis under REACH?

TEXT BY NEDYU YASENOV

Socio-economic analysis is an integral part of the authorisation and restriction processes introduced by REACH. Its main purpose is to support ECHA's opinion and the European Commission's decision making by describing the impacts of choosing one course of action over another.

This may include impacts on industry, workers, consumers, regulators and the environment. As chemicals play a central role in our society, it is crucial to evaluate both the costs and the benefits related to any proposal affecting their uses in an appropriate manner.

WHAT IS SOCIO-ECONOMIC ANALYSIS?

Within the framework of REACH, socio-economic analysis (SEA) supports decision making by considering whether society would benefit from:

- a restriction being adopted (compared to continued use or other risk management options); or
- an authorisation being granted for continued use of a substance of very high concern (compared to refusing the authorisation).

SEA assesses the impacts of a change against what would happen if the change did not occur. In an application for authorisation for example, this could involve comparing a situation where the applicant continues using a substance of very high concern with a situation where it would be substituted with a safer but less effective one. The change-over may require investment and result in increased costs for both the company and other actors in its supply chain.

© FOTOLIA

Socio-economic analysis is about assessing the impacts of a change against what would happen if the change did not occur.

HOW ARE THE IMPACTS ASSESSED?

Regulatory risk management tends to result in higher costs but also greater benefits. It is important to know who will be affected by a measure and what the consequences for the various actors will be.

The starting point for the SEA is an assessment of the affected companies' options, if they were not able to use the substance in question. As this essentially includes an analysis of alternatives, the net costs of adopting any such alternative substance or technology are crucial. Their assessment should be as realistic as possible, considering the companies' actual context (such as their technologies, location, markets) and decision-making processes.

Various methodologies exist to analyse the impacts. In the context of restrictions and applications for authorisation, cost-benefit analysis and cost-effectiveness analysis are two of the most widely-used methods.

Cost-benefit analysis converts all benefits into monetary units so that they can be directly compared to the costs. The conversion is based on valuation techniques that derive the willingness-to-pay (WTP) to avoid certain health risks or environmental damage. Cost-effectiveness analysis, on the other hand, compares the impacts (in their natural units) to the costs.

An example is the abatement cost per unit of emission of the chemical substance. Cost-effectiveness analysis is often used when the health or environmental impacts of the use of the chemical are either unknown or cannot be expressed in money equivalents. Sometimes the impacts can only be described in a qualitative, or semi-quantitative, manner. In these cases, one may still assess the compliance cost.

SEA can be complemented by a distributional analysis, which tells who would gain and who would lose from the regulatory

action. For example, some chemicals manufacturers may lose business due to a restriction. At the same time, there may be market opportunities for those manufacturers that produce alternative, safer substances.

Hence, the impacts of the restriction are shared unevenly by different industries, social groups, and/or regions. If the expected impact on a specific group is disproportionally high, this might be factored into the overall SEA.

To sum up, a high-quality SEA should be conducted and presented in an unbiased way to support, not replace, the opinion and decision making. It should naturally describe uncertainties and assumptions. SEA always requires multi-disciplinary expertise as it relies on information related to a wide range of issues, such as technical processes, business strategy, market analysis, health and environmental impacts and valuation techniques.

What ECHA does

ECHA's Risk Management Implementation Unit currently has a team of seven staff members who carry out socio-economic analysis. This team is responsible for the methodological development and support to ECHA, including its Committees.

ECHA has also carried out and published several studies related to methodologies and approaches for analysing the socio-economic impacts of chemicals regulation.

ECHA's Committee for Socio-economic Analysis (SEAC) evaluates applications for authorisation (as well as comments received in the public consultation) to formulate their opinions on whether the related socio-economic benefits outweigh the risks of continued use of a substance of concern. It also evaluates restriction proposals in a similar manner to evaluate if the costs of the proposed restriction are proportionate to the risk reduction. SEAC works in close cooperation with the Committee for Risk Assessment (RAC) and bases its assessment of the risks on the conclusions of RAC. Their opinions are sent to the European Commission for decision making.

Further information:

Socio-economic analysis in REACH
http://echa.europa.eu/support/socio-economic-analysis-in-reach

Committee for Socio-Economic Analysis
http://echa.europa.eu/about-us/who-we-are/committee-for-socio-economic-analysis

Preparing your application for authorisation
http://echa.europa.eu/applying-for-authorisation/start-preparing-your-application

Guidance for Socio-economic analysis – Restrictions
http://echa.europa.eu/guidance-documents/guidance-on-reach?panel=searest#searest

Guidance on the preparation of an application for authorisation
http://echa.europa.eu/guidance-documents/guidance-on-reach?panel=auth-appl#auth-appl

Terminology – in 23 languages
http://echa-term.echa.europa.eu/

DID YOU KNOW?

SEA and restrictions

In the restriction process, the proposing Member State (or ECHA on request of the European Commission) is responsible for the SEA. It should cover in particular the additional cost due to the restriction and the associated human health or the environmental impacts. Social and broader economic impacts and consequences for society as a whole are sometimes also described. The result of the SEA is documented in the Annex XV restriction report, which is scutinised by SEAC and RAC. It is also posted on ECHA's website for comments for six months. Overall, SEA is helpful in demonstrating if the costs are proportionate to the benefits of the restriction, and if there are any particular reasons for time limited or permanent derogations.

SEA and authorisation

A company or a group of companies is responsible for the SEA as part of their application. While the REACH Regulation does not require applicants to present a SEA, so far, all applicants have done one. As SEA is closely linked with the analysis of alternatives, ECHA has recently provided a recommended format which makes it easier for the applicants to document their SEA and the analysis of alternatives in a single document. SEA is used by SEAC when it gives its recommendation to the European Commission on the duration of the review period for an authorisation to use a substance.

ECHA Helpdesk's top tips: What do importers of chemicals need to know?

TEXT BY ANCA-MIRELA PETRISOR

Are you importing chemicals from outside the EU at volumes above one tonne per year? If you are, you may have to register them with ECHA. The same applies if you import mixtures. All substances in that mixture have to be registered individually. In addition, imported articles may contain substances that need to be registered if specific conditions apply. Here are the answers to the most frequently asked questions.

I import chemical substances and mixtures. Do I have to register under REACH?

Yes you do. To start with, you need to clarify the origin of the substance, which you import as such, in a mixture or in an article you import. If you import a substance from a non-EU country, then it needs to be registered.

You need to know the identity of your substance or the substances in your mixture or article. In general, for importers of individual substances, determining the identity of the substance is more straightforward than for those who import mixtures.

Registration is per substance, covering the tonnage spread over the different mixtures in which the substance in included. This means that if you import several mixtures all of which have one ingredient in common, you need to sum up the tonnage of such an ingredient from each mixture.

Registration is also per company: even if another importer has registered the same substances as you, you need to have your own registration. However, you will need to get in contact with other companies importing or manufacturing the same substance and work together to prepare a joint registration.

I import an article. Do I need to register it?

You do not have to register the article, but you need to register a substance that is in the article if:

- the substance is intended to be released from the article during normal or reasonable use (for example, scented toys) and
- the total amount of the substance present in all articles exceeds one tonne per year, and
- the substance has not been registered for the same use by any other company.

You will also need to notify ECHA if your article contains a substance of very high concern (SVHC). Your non-EU based manufacturer needs to give you this information. All SVHCs are listed on the Candidate List on our website.

My non-EU supplier has appointed an EU-based Only Representative. Do I still need to register my substance?

If your supplier has appointed an Only Representative, this representative will have to register the substance. Under REACH, you are a downstream user and so you will have to comply with other obligations. For example, you will need to provide safety data sheets for your substances and mixtures.

We recommend that you keep track of the agreements and communications between you, the non-EU based company and the Only Representative. You need to know who the Only Representative is and how much of your volume is covered by their registration.

If the Only Representative fails to fulfil its registration obligations, you have to register the substance yourself to stay legally on the market.

Futher information:

REACH 2018
http://echa.europa.eu/reach-2018

Guidance on registration
http://echa.europa.eu/web/guest/guidance-documents/guidance-on-reach?panel=registration#registration

DID YOU KNOW?

The REACH Regulation not only applies in the EU but also in the European Economic Area (EEA). This means that Iceland, Liechtenstein and Norway also apply the rules of REACH.

Chemical trade between the EU Member States and the three EEA countries does not count as import or export.

WHO IS AN IMPORTER UNDER REACH?

You are an importer if you buy a chemical product directly from a supplier based outside the EEA and bring it into the EEA territory. Your responsibility is to make sure that the chemicals and products you import comply with the EU chemicals legislation.

Read more on the 'Getting started with the EU chemicals legislation' web pages: http://echa.europa.eu/en/support/getting-started/importer

Your experience of Article 95

TEXT BY HANNA-KAISA TORKKELI

1 September 2015 marked a deadline for companies to be included on the list of active substances and suppliers, known as the Article 95 list. By that date, ECHA had received 158 applications to be included on the list. We asked some of our stakeholders about their experience of dealing with the Article 95 requirements.

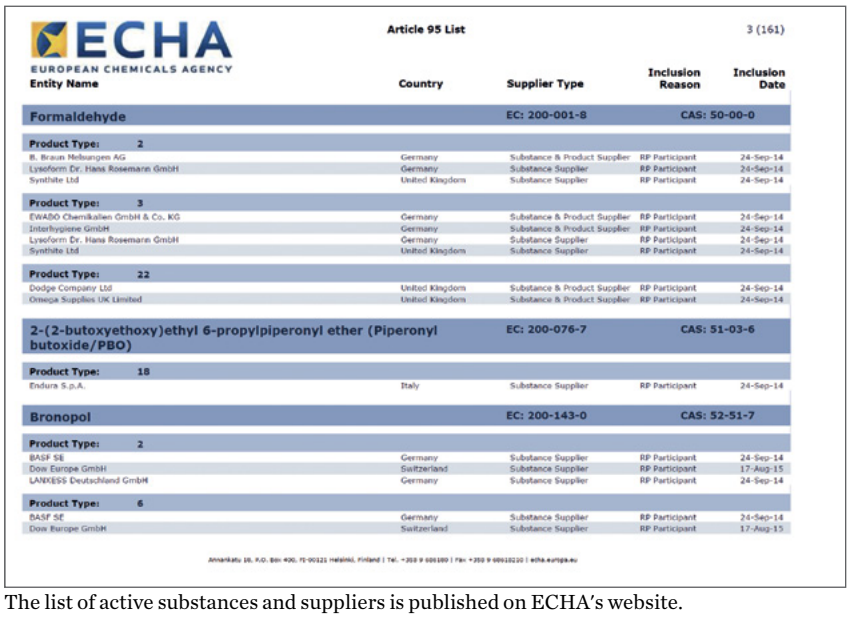
Ms Flore Cognat of the European Chemical Industry Council, Cefic, says that information on the Article 95 requirements only started spreading in late 2014.

"We still get many enquiries from companies, so I'm sure applications for inclusion on the list will continue to come. For example, the legal clarification for *in situ* active substances came quite late for the data owners and the third parties to adapt and understand what they needed to do," she says.

Dr Thomas Leopold, a consultant at Ecomundo, says that small and medium-sized companies (SMEs) have especially had problems with the complexity of the process, the cost of data and with the IT tool R4BP 3.

"There are also strategic issues relating to the trade of the products. If a company chooses to apply to be on the list and buys a letter of access (LoA) to get access to the data, it cannot go back anymore. You cannot resell the LoA. Companies have needed help in figuring out what is the right strategy for them."

He says his consultancy is still dealing with various Article 95 dossiers. "Some companies came to us very late. We tell them that there is no need to panic, but that they should really speed up. The European Commission has recommended that the enforcing Member States give the companies 'a period of grace' of six months to comply with the requirements."



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Article 95 List — 3 (161)

Entity Name	Country	Supplier Type	Inclusion Reason	Inclusion Date
Formaldehyde		EC: 200-001-8	CAS: 50-00-0	
Product Type: 2				
B. Braun Melsungen AG	Germany	Substance & Product Supplier	RP Participant	24-Sep-14
Lysoform Dr. Hans Rosemann GmbH	Germany	Substance Supplier	RP Participant	24-Sep-14
Synthite Ltd	United Kingdom	Substance Supplier	RP Participant	24-Sep-14
Product Type: 3				
EWABO Chemikalien GmbH & Co. KG	Germany	Substance & Product Supplier	RP Participant	24-Sep-14
Interhygiene GmbH	Germany	Substance & Product Supplier	RP Participant	24-Sep-14
Lysoform Dr. Hans Rosemann GmbH	Germany	Substance Supplier	RP Participant	24-Sep-14
Synthite Ltd	United Kingdom	Substance Supplier	RP Participant	24-Sep-14
Product Type: 22				
Dodge Company Ltd	United Kingdom	Substance & Product Supplier	RP Participant	24-Sep-14
Omega Supplies UK Limited	United Kingdom	Substance & Product Supplier	RP Participant	24-Sep-14
2-(2-butoxyethoxy)ethyl 6-propylpiperonyl ether (Piperonyl butoxide/PBO)		EC: 200-076-7	CAS: 51-03-6	
Product Type: 18				
Endura S.p.A.	Italy	Substance Supplier	RP Participant	24-Sep-14
Bronopol		EC: 200-143-0	CAS: 52-51-7	
Product Type: 2				
BASF SE	Germany	Substance Supplier	RP Participant	24-Sep-14
Dow Europe GmbH	Switzerland	Substance Supplier	RP Participant	17-Aug-15
LANXESS Deutschland GmbH	Germany	Substance Supplier	RP Participant	24-Sep-14
Product Type: 6				
BASF SE	Germany	Substance Supplier	RP Participant	24-Sep-14
Dow Europe GmbH	Switzerland	Substance Supplier	RP Participant	17-Aug-15

The list of active substances and suppliers is published on ECHA's website.

SHARING DATA AND ITS COST

The sharing of data between those companies already on the list and the alternative suppliers has raised a lot of questions.

"Companies are asking me what is my role, what do I need to do, how can I be compliant? Some of them are not quite sure what they need – the obligations are different depending on their role. But in general, from what I've seen, the intentions from both sides to come to an agreement on data sharing are good," Ms Cognat explains.

Stefaan Verschaeve from Sopura – an SME offering hygiene and water treatment solutions – says his company, which is already on the list, received a lot of requests for sharing data. "The discussions, even with our competitors, have been very constructive. The data sharing really works. Of course, I admit that we are dealing mainly with big companies," he says.

On the other side of the coin, the room for negotiation might be almost non-existent. "There are three parts that make up the price: the cost of studies, the evaluation of the active substance dossier by the Member State, and the cost of the dossier management. For the first two, we are able to ask for details, but as for the cost for managing the dossier, we have no say. We cannot really argue to lower this cost," Dr Leopold says.

Determining the overall costs of sharing data is not always straightforward. This is the case especially if the data owner has supported the active substance for several years as a participant of the review programme. "The aim is equitable compensation. An alternative supplier may only now be interested in

the data that the review programme participant has been collecting for the past 10 years. That work needs to be compensated," Ms Cognat points out.

Ecomundo has seen some very interesting cases with companies aiming to cut down on the cost of compliance with the Biocidal Products Regulation (BPR).

"Companies have formed partnerships to be able to share the cost for inclusion in the Article 95 list. For example, a European shoe retailer may want to have anti-mould paper to protect the shoes they are selling. The supplier of this paper is a small non-EU company who cannot afford the cost of the LoA. The shoe retailer and the supplier of the anti-mould paper form a partnership where they share the costs of the LoA and sign a commercial exclusivity contract. Afterwards, the shoe retailer can resell the anti-mould paper to other suppliers to get income to cover the costs of the LoA," Dr Leopold explains.

OTHER MANAGEMENT OPTIONS

Altogether, half of Ecomundo's clients have stopped marketing certain products because of the Article 95 requirements.

"Unfortunately, these are small companies, who have tried to do their best with limited resources. They have engaged in research and development to develop their products and afterwards have had to discontinue. I also worry that if the number of active substances decreases, we may see more resistance from targeted microorganisms and parasites."

One fifth of Ecomundo's customers chose to change their products or to reduce their product range to focus on other legislation. 30% chose to apply for the Article 95 list.

"We have worked with companies who chose to target borderline products. One example is about the commercialisation of a hydro-alcoholic gel. The company could not afford the LoA so they changed their product. It became a sanitiser instead of a disinfectant and therefore required compliance with the Cosmetics Regulation and not the BPR. Another example is a company that decided to focus only on the medical device market," Dr Leopold concludes.

ARTICLE 95

Companies that have submitted a dossier for an active substance under the Biocidal Products Directive (BPD) or the Biocidal Products Regulation (BPR) that has been validated by a Member State are on the list of active substances and suppliers – as are companies with an approved Article 95 application.

To be able to make a biocidal product available on the market, the company needs to be listed or buy the active substance from somebody who is listed.

ECHA will continue updating the Article 95 list each month to include suppliers whose applications are decided upon after 1 September 2015. These cases include late applicants, new market entrants and new relevant substances. ECHA also publishes a list of the pending applications, which tells industry and other stakeholders who has applied but who has not yet received a final decision.

Further information:

List of active substances and suppliers
http://echa.europa.eu/information-on-chemicals/active-substance-suppliers

List of pending applications
http://echa.europa.eu/documents/10162/17287015/active_substances_list_of_pending_app_en.pdf

Guidance on biocides legislation
http://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation

R4BP 3 – Register for Biocidal Products
http://echa.europa.eu/support/dossier-submission-tools/r4bp

ECHA Helpdesk contact form
http://echa.europa.eu/contact/helpdesk-contact-form

Terminology – in 23 languages
http://echa-term.echa.europa.eu/

Union authorisation "a flag of confidence" for European companies

TEXT BY HANNA-KAISA TORKKELI

Union authorisation of biocidal products – a new concept introduced by the Biocidal Products Regulation (BPR) – has been in place now for little over a year. Companies can get authorisation for their biocidal products in all Member States with just one application. We asked our stakeholders in what situations this EU-wide authorisation works best.

The main reason for applying for Union authorisation is to get easy and quick access to the whole EU market. For *Stefaan Verschaeve's* company Sopura – an SME offering hygiene and water treatment solutions – being able to operate EU-wide is a clear business benefit.

"We are in business with big multinationals. Their calls for tender might easily cover 10 plants in many countries. When we are able to say that we already have an authorisation in those countries for our product family, we have a strong competitive advantage. If we win the tender, we can immediately start our operations. It is a quicker and easier way to immediately activate the business that you commercially gain," Mr Verschaeve says.

Dr Thomas Leopold, a consultant at Ecomundo agrees that Union authorisation is a 'flag of confidence' for the companies' customers. "For the companies' clients, Union authorisation gives reassurance to do business with them."

BIG COMPANIES ALREADY SEE THE BENEFITS

Although Sopura as an SME is going for Union authorisation, Mr Verschaeve believes that it is still mostly for big companies. "Big multinationals are convinced about it, but for most SMEs, it's less clear. For them this legislation seems to be about investing money without additional commercial benefit. But if the SME is really doing business

© FOTOLIA

Union authorisation gives access to the whole EU market at one go.

in many EU countries, they really need to take advantage of it. At the end of the day, it is not only a question of finance but also of believing that this helps you to maintain and grow your business."

According to Dr Leopold, large companies go for Union authorisation for two reasons: "Firstly, the number of actors in the market is reducing mainly because of the Article 95 requirements. So, the big actors are taking a bigger share. Secondly, it comes down to the fees. I think SMEs will continue applying for national authorisations or same product authorisations."

The cost of Union authorisation needs to be compared with the costs of many national authorisations or mutual recognitions. Ecomundo's advise to its clients is straightforward.

"We recommend that companies choose Union authorisation if they target 10 or more countries. That's the general rule."

FLEXIBILITY AND TIMING

Union authorisation can be applied both for a single biocidal product or a product family with similar conditions of use across the EU. There is also the possibility of extending the product family by adding new products which respect the agreed conditions of use.

"This is very important to us. We sell customised hygiene solutions, which means that we need to understand the circumstances our customers have in terms of hygiene and microbiology. And this is often linked to the products they are making. To meet their needs, we might want to adjust the product formulation. We hope that ECHA does not take too strict an approach to the family concept," Mr Verschaeve explains.

Another concern of Sopura is that it may take up to two years before the Union authorisation is granted.

"In the meantime, we might get business opportunities in countries in which we don't have national authorisation. But we cannot do anything before we have the final approval. Perhaps it would be possible to have a temporary authorisation governed by ECHA in cases where specific business opportunities arise before the final authorisation is granted. This could encourage more companies to go for Union authorisation."

Further information:

Union authorisation
http://echa.europa.eu/regulations/biocidal-products-regulation/authorisation-of-biocidal-products/union-authorisation

Guidance on biocides legislation
http://www.echa.europa.eu/en/guidance-documents/guidance-on-biocides-legislation

Terminology – in 23 languages
http://echa-term.echa.europa.eu/

Guest column | Bonnie Okeke, Head of Regulatory affairs, GOJO Industries-Europe

Life after the Article 95 deadline – perspectives of a stakeholder

At this stage of the Biocidal Products Regulation (BPR), it is probably reasonable to assume that most stakeholders know that it has replaced its predecessor, the Biocidal Products Directive. Since its implementation on 1 September 2013, the BPR has progressed in phases with staggered critical deadlines.


Dr Bonnie Okeke.

The most recent was the Article 95 deadline of 1 September 2015. The activities by ECHA and various Member States to raise awareness and urgency ensured that the date lived up to its regulatory landmark.

Article 95 created an obligation for all biocidal actives and product manufacturers or importers in the EU to make sure they are on the List of active substances and suppliers by 1 September. If they are not on the list, they have to remove the active substances or products containing them from the market. http://echa.europa.eu/information-on-chemicals/active-substance-suppliers

It is important to reiterate the purpose of the list: it makes clear which companies, big and small, place biocidal active substances or products in the EU market. It also ensures they are treated equally and avoids uneven market access and distortions to trade that have been caused by 'free riders' who reap the benefits without contributing information.

IS EVERYONE ON THE LIST WHO NEEDS TO BE?

The most recent Article 95 list of 2 November contains a considerable number of biocidal active substances and products manufacturers and suppliers. However, there are still concerns about the number of active substances and products that would eventually be supported and remain on the market in the medium to long-term due to technical challenges and cost pressures.

It seems too early for a post-mortem since some companies might be on the list of pending applications. Though of doubtful legal standing under the BPR, the pending list also helps transparency. However, until they finally make the official list, there are bound to be concerns. http://echa.europa.eu/documents/10162/17287015/active_substances_list_of_pending_app_en.pdf

FUTURE CHALLENGES

The immediate considerations under the BPR include how to protect critically important active substances where the manufacturers are outside the EU and have no bottom-line interest in being listed. This is where companies need to work with others, who have similar goals of legal survival and market continuity for active substances and products in the EU market. This includes competitors too.

Legal survival is important because these active substances and products may not have changed during their physical and chemical life cycle including in their risk profile.

Consortia provide the platform for ensuring the process, developing common dossiers for specific active substances, achieving substantial cost synergies through data-sharing negotiations even in difficult situations. The latter has enhanced the spirit of the BPR data-sharing obligations. Non data owners still require this important legal protection.

Another thing to consider is how stakeholders can avoid 'campaign fatigue'. A time tested principle is handy; communicate, communicate and communicate again, changing the content, language and style appropriately. Tailored and targeted presentations, workshops, summits, seminars and webinars are helpful tools. An early buy-in from each stakeholder is crucial. Implementation is an ongoing process as new active substances are assessed, approved or disapproved.

The content must retain the interest, focus and commitment of each audience. Though a complex regulation, each functional stakeholder is involved in different parts or stages of the regulation and needs to understand and use the supplementary materials provided, including the guidance documents.

Dr Bonnie Okeke, Ph.D. PG. Dip Law, Head of Regulatory Affairs

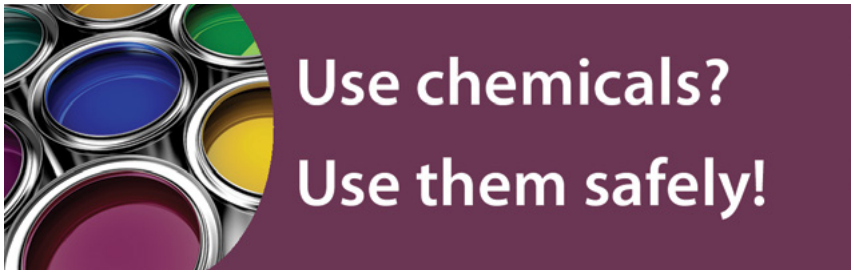
GOJO Industries-Europe is a leading manufacturer, importer and distributor of hygiene and skincare products in the EU. Its American parent company GOJO Industries Inc. is well known for its PURELL® brand alcohol based hand sanitiser products. The company was founded in 1946 and has its headquarters in Akron, Ohio.

GOJO is on the Article 95 List of active substances and suppliers. https://www.gojo.com/

Safety data sheets and SUMIs - are you up-to-date?

TEXT BY MONIQUE PILLET

Communication throughout the supply chain is at the core of REACH. Safety data sheets are the main means to do that. SUMIs - Safe Use of Mixture Information - templates are the new arrival. Are you up-to-date?



How thoroughly should I check the information in the safety data sheet (SDS) received from my supplier?

You should be able to judge whether the information is reliable. Check that the SDS is up-to-date, that it is consistent throughout and in line with the labelling information. Make sure also that it contains the information you need under the various sections .

You should be confident that the content of the SDS complies with the requirements of REACH to identify, apply and recommend risk management measures. You should also recognise if you need to communicate new information on hazardous properties or any other information that may affect the risk management measures identified in the SDS to your supplier.

I manufacture the substance for my own use only and do not supply it to any customers. Do I need to do a REACH compliant SDS for my workers?

You are not a supplier, so you don't need to provide an SDS.

However, as an employer, you do have to give information to your workers, for example, on the hazardous chemical agents and appropriate risk management measures. You need to find an appropriate and documented way to do this.

Where is the SUMI (Safe Use of Mixture Information)* template available?

The template is being developed by the Downstream Users of Chemicals Co-ordination group (DUCC) and should be made available by the end of 2015.

For an overview, have a look at a recent material presented at the meeting of the Exchange Network for Exposure Scenarios (ENES): http://echa.europa.eu/documents/10162/21878363/enes_8_sumi_en.pdf

A library of SUMIs, containing sector-specific advice for common uses and based on an agreed template, is also under development. The first batch will be available on the DUCC website in the end of 2015 or early 2016. Contact DUCC if you would like to get involved in this project.

As a downstream user/formulator, do I have to supply SUMIs to my customers or are the SDSs enough?

If a safety data sheet is required for a mixture, you must provide it to your customers. You also have to provide relevant information from the exposure scenarios of the constituent substances. A SUMI is one way you can do that. Other options include incorporating the information in the SDS or by forwarding the relevant exposure scenarios.

Should I prepare a DU chemical safety report when I have new uses for a substance that is not classified as hazardous and the supplier does not react to my plea to include these new uses in an update of his registration dossier?

If the substance is not classified as hazardous, there is no legal obligation to prepare a chemical safety report. If the substance is hazardous, check chapter 4 of the *Guidance for downstream users* for more information about your obligations.

* The Safe Use of Mixture Information is an approach being developed at the sector association level that harmonises the communication of safety advice for mixtures. It aims to provide easy to understand and consistent advice to end users of chemicals on how to use hazardous mixtures safely. SUMIs will not replace safety data sheets (SDS) but can be annexed or integrated into the SDS.

AUTHORISATION

As a downstream user using a substance that is on the Authorisation List in a mixture with a concentration below the classification levels, do I have to submit an application for authorisation to continue using the substance?

Uses of substances when they are present in mixtures below the applicable concentration limits do not require authorisation. Formulation of a mixture requires authorisation (by the formulator or an actor up the supply chain), unless a generic exemption applies (*see Q&A 1027 and 1030*).

DOWNSTREAM USER CHEMICAL SAFETY REPORT (DU CSR)

What length does ECHA expect the 'normal' DU CSR on unsupported use to be?

There is no general rule for the length of a DU CSR. It is the content that matters. The length depends on the complexity of the case. Examples/excerpts are given in *Practical Guide 17 on How to prepare a downstream user chemical safety report*.

In what language should I write the DU CSR?

The DU CSR is an internal company document and you are free to choose the language. However, remember that your national authorities may request to see it.

If you supply the substance as such or in a mixture to your customers (except the general public), the relevant exposure scenario annexed to the SDS must be supplied in the official language of the Member State where the substance or mixture is placed on the market. Fore more details see chapter 8 of *Practical Guide 17 on How to prepare a downstream user chemical safety report*.

Do I need to submit my DU CSR when reporting an unsupported use to ECHA?

Downstream users do not need to submit their DU CSR to ECHA. Information about the use is submitted to the Agency in the downstream user report (*see Q&A 487*).

Is the information submitted on the use known only by the DU and ECHA?

This information is confidential but is made available to the Member State authorities when required for regulatory risk management decision making. An overview of the DU reports on ECHA's website reports statistics only.

USING INFORMATION

Can I use the information published from dossiers on ECHA's website? How can I contact the data owner?

You need to contact the registrant if you want to use the information, such as including it in a publication.

The names of the registrants are included in the registered substances database. You need to contact the registrant directly and discuss the possibility of using the data. Once you have permission from the data owner, you can use the data.

These questions were asked during the downstream user webinar ECHA held in October. Check out the webinar recording and other material at:
http://echa.europa.eu/view-webinar/-/journal_content/56_INSTANCE_DdN5/title/downstream-user-update

Further information:

Exchange Network for Exposure Scenarios (ENES)
http://echa.europa.eu/about-us/exchange-network-on-exposure-scenarios

CSR/ES Roadmap
http://echa.europa.eu/regulations/reach/registration/information-requirements/chemical-safety-report/csr-es-roadmap

Downstream user guidance
http://echa.europa.eu/documents/10162/13634/du_en.pdf

Downstream Users of Chemicals Co-ordination group (DUCC)
http://www.ducc.eu/Home.aspx

Questions & answers
http://echa.europa.eu/support/qas-support/qas

Practical Guide 17
http://echa.europa.eu/documents/10162/13655/pg17_du_csr_final_en.pdf

Checklist for safety data sheets
http://echa.europa.eu/documents/10162/966058/sds_checklist_en.pdf

Terminology – in 23 languages
http://echa-term.echa.europa.eu/

CLP mixtures deadline – feedback from the detergent and maintenance product industry

TEXT BY ADAM ELWAN, SYLVIE LEMOINE A.I.S.E.

Mixtures being placed on the EU market had to be reviewed by 1 June 2015 according to the Classification, Labelling and Packaging (CLP) Regulation. This meant more safety information for the users of the products but new challenges for mixture manufacturers. We spoke with *Dr Sylvie Lemoine* from the International Association for Soaps, Detergents and Maintenance Products (A.I.S.E.) to find out about how industry managed.

Dr Sylvie Lemoine of A.I.S.E. says that the deadline for mixture producers to comply with CLP had a 'major impact' on industry.

Did companies manage to update the classification and labelling of their products in time?

Yes, most of A.I.S.E.'s member companies managed to re-label their products in time, with large companies reaching close to full compliance with the deadline. The two-year transition period, allowing products placed on the market before 1 June 2015 to still be labelled according to the former Directive, helped us to reach a high level of compliance. This means that products already 'on the shelves' (meaning 'in the supply chain') can be sold with their old labels and do not need to be recalled or wasted. This is particularly useful for slow-moving goods.

However, for small and medium-sized companies, the outcome was more diverse. Companies with many labels to update and limited resources, or those producing for other brands (for example private labels) faced particular difficulties.

Companies had to find additional staff to manage the deadline. In some cases, this meant redeploying staff within their company. This has led to a reduced number of new product launches, which is the main economic driver for our sector.

What were the main challenges?

As CLP has generally introduced more severe classification criteria and more classification endpoints, products that have previously not needed classification, have had to be classified.

Optimising workload and supply chain management has been a considerable challenge because of production constraints due to demand in our fast-moving consumer goods sector, and lack of clarity on how to manage stocks due to diverging interpretations of 'placing on the market' in different countries.

All of our members also said that there was a lack of classification information from the suppliers or that if the information existed, it was delivered too close to the 1 June deadline and could no longer be taken into account when relabelling the products.

The new requirements for labelling different packaging layers and managing inner package labelling were quite laborious to implement. Some companies had to integrate other regulatory requirements such as the Biocidal Products Regulation at the same time and update their safety data sheets with the new information. Producers of laundry unit doses had to rush to implement new manufacturing, labelling and packaging requirements with the same deadline as CLP relabelling.

SMEs in particular reported that designing labels with more text as well as the selection of precautionary statements was often a burden. Resources were tight as companies were coordinating the generation of new labels while producing products and, at the same time, trying to meet the deadline.

Another aspect was explaining the label changes to retailers and clients. This was in particular difficult when the label changed and more severe classification applied, but the product formulation stayed the same. Some customers did not want to accept the new labels.

What is next for your sector in the classification and labelling of mixtures?

Reviews and updates are already foreseen as new information becomes available. This applies in particular for new classifications of the raw materials for mixtures.

With REACH leading to new data generation, companies will need more frequent updates in the coming years than was the case under the Dangerous Preparations Directive. In some cases, the classification updates will have far-reaching consequences, for example inclusion of new sites in the scope of the Seveso Directive for the management of major-accident hazards.

Upcoming harmonised reporting to poison centres and the introduction of a unique product identifier will be another significant change to manage at company level, and will require relabelling.

In addition, there are still some uncertainties on the horizon, such as the understanding of the new pictograms by consumers, the classification and labelling of products with extreme pH values and explaining and implementing CLP in non-EU countries where the same packaging and labelling may also be used.

What were the lessons learnt from the point of view of the detergent and maintenance product industry?

Some of the new CLP requirements that were considered 'relatively minor' when CLP was introduced, turned out to have a major impact. Comparing the actual costs to the cost-benefit analysis that was done at the early stage of CLP would be interesting.

Mixtures being placed on the EU market had to be reviewed by 1 June 2015 according to the CLP Regulation. This resulted in more safety information for the users of the products, and at the same time new challenges for mixture manufacturers.

In addition, harmonising definitions and requirements between the different legislation as well as clarifying interpretations of the law at EU level (for example placing on the market and the bridging principles) would have helped to reduce misunderstandings and workload. Industry is still facing too many national divergences of interpretation, which adds uncertainty to an already complex situation. Multiple labelling requirements from multiple pieces of legislation should also be revisited in particular concerning the labelling of ingredients.

To manage the upcoming changes in classification and labelling, companies should maintain very clear processes and tools with product lists and stock management.

As for the regulators, my message is clear: there needs to be three compliance deadlines for any future change impacting classifications – one for substances, one for intermediary mixtures (also called mixtures in mixtures) and one for end-use mixtures.

Dr Sylvie Lemoine is the Director of technical and regulatory affairs at A.I.S.E, which is the voice of the Soaps, Detergents and Maintenance Products industry in Europe. A.I.S.E.'s membership totals 31 national associations, covering about 900 companies ranging from small and medium-sized enterprises to large multinationals. Biocidal products manufactured by A.I.S.E. members include a vast range of disinfectants for household and institutional use, as well as household insect control products. http://www.aise.eu.

Further information:

CLP Regulation
http://echa.europa.eu/regulations/clp

CLP pictograms and quiz
http://echa.europa.eu/chemicals-in-our-life/clp-pictograms

Dangerous Preparations Directive
http://ec.europa.eu/enterprise/sectors/chemicals/documents/classification/archives/dangerous-preparations/directive_en.htm

Terminology – in 23 languages
http://echa-term.echa.europa.eu/

Guest column | Anne-Sofie Andersson, Director, ChemSec

Five reasons why substituting hazardous chemicals saves you money

Substituting hazardous chemicals with safer alternatives is of course beneficial for both health and the environment, but what's often overlooked is that it can also be a really smart business move.

Anne-Sofie Andersson.

1. Staying ahead of regulation gives a competitive advantage
When a chemical is banned or restricted there is no option but to manage without it. So, your business should be on the fence opposing stricter regulation, right?

Well, looking at the EU market, the countries with the strictest national chemical regulations – Finland, Denmark, Germany and Sweden – are, according to the Eco-innovation index 2012, actually the ones who lead in eco-innovation. Similarly, the strictest regulations in the United States are found in states like California, New York and Massachusetts. Some people argue that these regulations make companies move away, choosing locations with less regulation. But when you look at venture capital, this is not the case. In fact, areas with strict environmental regulation have the highest venture capital. (See http://www.citylab.com/work/2013/07/americas-leading-venture-capital-area-codes/5091/)

2. Safer alternatives win in the long run
Innovations are costly in the beginning while over time the price of production declines.

During the initial phase, ideas are generated and tried, and problems are found and solved. When everything is operating smoothly, the production can increase and become less costly.

H&M, for example, replaced fluorinated hydrocarbons (FCs) with alternatives to gain a water-repellent function on certain products. At present, the difference in price between the FC and the FC-free technology is not significant, but the productivity has increased and there is less cleaning needed for the equipment, also leading to savings.

3. Use of hazardous chemicals results in additional costs
Comparing the price of a hazardous chemical and an alternative may seem relatively straightforward. However, it's not such a simple comparison because using hazardous chemicals results in additional costs.

Take the construction company Skanska, for example. By changing an injectable mortar product containing problematic chemicals, they removed the need for special training for workers, additional health examinations and costly waste treatment.

4. The general market trends moves towards sustainability
Danish retailer Coop decided to take microwave popcorn off the shelf – the PFC lining in the packaging can have negative health effects. The move meant that Coop lost more than two million euros in annual turnover.

The losses, however, were immediately offset by the great press coverage that the move generated, estimated to be worth even more from a communications perspective. Half a year later, the very same supplier came back with an improved product without any PFCs. The popcorn has now returned to the shelves, with an overwhelmingly positive reception.

5. Scandals are extremely costly
Having to withdraw products from stores due to either non-compliance with regulation or worries among consumers is a nightmare for any company. Product recalls, falling stock prices and damaged brand reputation are just some of the consequences we see happening time and time again, with Dieselgate being the latest and greatest example.

Anne-Sofie Andersson, Director

The International Chemical Secretariat (ChemSec) is a non-governmental organisation founded in Sweden in 2002. It advocates for stricter regulatory control on potentially hazardous chemicals and works with businesses to reduce the production and use of hazardous substances in their products and supply chains. ChemSec maintains the SIN List, identifying hazardous substances likely to be restricted under REACH.
www.chemsec.org

Subsport: http://www.subsport.eu/
ECHA's substitution web pages: http://echa.europa.eu/regulations/substituting-hazardous-chemicals
Painting a safer Europe:
https://www.youtube.com/watch?v=Zs8oPSXdU5U
Webinar Why opt for substitution:
http://echa.europa.eu/view-webinar/-/journal_content/56_INSTANCE_DdN5/title/why-opt-for-substitution

REACH improves trust in chemicals management

INTERVIEW BY HANNA-KAISA TORKKELI

Although the REACH registration journey is yet to cross its finishing line, some positive impacts of the EU-wide regulation can already be seen.

One of the most prominent benefits of REACH is that it has created a level playing field for industry across Europe. The companies and authorities around Europe now share the same aims.

"I see REACH as a learning process for the European chemical companies as well as for authorities. The best solutions are those coming from joint initiatives of industry and authorities," says *Dr Erika Kunz*, Head of Global Registration and Evaluation of Chemicals at Clariant.

Ms Gertraud Lauber from the German trade union IG Bergbau, Chemie, Energie (IG BCE) has seen the impact of REACH in companies since 2007.

"The mindset and attitude towards REACH has completely changed. After REACH was introduced, companies and workers in Germany started to panic about losing jobs, mainly because of the listing of substances of very high concern (SVHC). They did not see the point of REACH – after all, they had already been handling their chemicals safely for many years."

However, as time passes, the positive effects of REACH have become more apparent. "Companies now know more about their substance properties and can move away from chemicals with toxic endpoints. Workers have become more interested in the substances they work with and how to handle them safely."

MORE DATA

REACH has already created an enormous amount of information on substances used in Europe. To date, almost 14 000 chemicals have been registered and information on nearly 13 500 substances has been published on ECHA's website.

"All this information can be used for future assessments, for example, by using intelligent tools that enhance the understanding of chemical substances through valid and robust read-across approaches," says Ms Kunz. She continues, "This knowledge is not only helpful for complying with REACH, but also for our research and development department who can select the most promising substance with both a high application performance and safe use."

SUSTAINABLE CHEMISTRY

The future of the European chemicals industry is in sustainable chemistry. As REACH makes companies look at their products in the long term, it also creates a competitive advantage for them in the global market.

"If you are a player in the global market, you have to use sustainable chemicals. REACH plays a big role in that – if you comply with REACH you can market your chemicals all around the world. REACH is actually no longer a threat to jobs but is creating them by driving for innovation, research and development," Ms Lauber explains.

BUILDING TRUST

Following the rules set by the regulation is beneficial to an individual employer's image and the overall reputation of the chemical industry.

© CLARIANT © ECHA

Dr Erika Kunz (left) and Gertraude Lauber.

"Workers trust companies that play by the book," Ms Lauber stresses.

"REACH gives us better possibilities to assess and manage chemical risks. At the same time, it also gives higher transparency for all stakeholders within the supply chain and beyond, with the potential to create greater confidence in the entire chemical industry," Ms Kunz points out.

Although REACH has found its way into the companies' daily routines, it cannot on its own make the world of chemicals safer.

"REACH is an overarching legislation. We also have the cosmetics, pharmaceutical and biocides regulations, which are all different. EU chemicals legislation needs more integration to be effective and consistent in the long term," Ms Lauber concludes.

Further information:

REACH at Clariant
http://www.clariant.com/en/Sustainability/REACH-at-Clariant

IG Bergbau, Chemie, Energie (IG BCE) (in German)
https://www.igbce.de/

REACH 2018
http://echa.europa.eu/reach-2018

Chemicals in our life
http://echa.europa.eu/chemicals-in-our-life

Austria tips the scale in favour of REACH

TEXT BY IRENE POZA LATORRE

REACH has resulted in an economic resource gain for the Austrian economy of about 2.5 billion euros.

This figure is based on a **cost-benefit analysis** to analyse and quantify the impact of REACH. This analysis takes health benefits, environmental benefits and indirect and direct costs of REACH into consideration.

The **economic effects** of REACH on Austria were analysed by comparing the current situation with a hypothetical scenario without REACH. It shows that the weighted average of individual price increase is low (0.006%) and there is a slight decline in macroeconomic indicators such as employment, private consumption and production.

However, it is stated that "the values are significantly lower than one-thousandth of the respective indicator of the Austrian economy".

REACH in general has had a positive impact on the quality and availability of information on chemicals. The study shows that – irrespective of the industry role or company size – REACH has improved customer relations, the awareness of hazardous substances as well as the exchange of information in the supply chain.

There is also a general tendency to change the product range to move away from hazardous substances. However, being compliant with REACH is still not yet perceived as a competitive advantage.

AUSTRIAN STUDY ON THE IMPACT OF REACH

The study 'REACH - Evaluation of the impact on the affected industry and the whole economy in Austria' was commissioned by the Austrian Federal Ministry of Agriculture, Forestry, Environment and Water (BMLFUW). It covers three issues: how REACH affects industry, how REACH affects the whole Austrian economy and the cost-benefit analysis of the REACH system.

Upcoming

November -December 2015

REACH 2018 webinar: 18 November
http://echa.europa.eu/view-webinar/-/journal_content/56_INSTANCE_DdN5/title/reach-2018-find-your-co-registrants-and-prepare-to-work-together

PBT (persistent, bioaccumulative and toxic substances) Expert Group meeting:
17-18 November
http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/pbt-expert-group

HelpNet REACH Workshop:
17-18 November
http://echa.europa.eu/en/about-us/partners-and-networks/helpnet

Committee for Risk Assessment:
24-27 November
http://echa.europa.eu/about-us/who-we-are/committee-for-risk-assessment

Committee for Socio-economic Analysis:
30 November – 4 December
http://echa.europa.eu/about-us/who-we-are/committee-for-socio-economic-analysis

Committee for Risk Assessment:
1-4 December
http://echa.europa.eu/web/guest/about-us/who-we-are/committee-for-risk-assessment

Member State Committee:
7-11 December
http://echa.europa.eu/about-us/who-we-are/member-state-committee

Biocidal Products Committee:
8-10 December
http://echa.europa.eu/about-us/who-we-are/biocidal-products-committee

Management Board meeting:
16-17 December
http://echa.europa.eu/about-us/who-we-are/management-board

Webinars:

http://echa.europa.eu/support/training-material/webinars

Global look at soil risk assessment

TEXT BY VEERA SAARI

A workshop on soil risk assessment brought over 200 experts to Helsinki in October to discuss the state of the art on how to assess the impact of chemicals on our soil. We interviewed three of the participants on why soil risk assessment matters.

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The workshop on soil risk assessment brought over 200 experts to ECHA in October.

José Tarazona, Head of the Pesticides Unit in the European Food Safety Authority, highlighted the importance of protecting soil – both from a societal and environmental point of view.

"Agricultural and forest soil is essential for producing food – from the farm to your fork. Ensuring biodiversity is also a key goal."

According to him, the main challenge at the moment lies in the complex interaction of chemicals within the soils. "There is much more complexity in soil risk assessment than, for example, in the aquatic environment. Soil is a very complex matrix that contains water, air and organic and mineral particles. All of these affect the fate of the chemical and its toxicity for different organisms."

For *Ilse Schoeters*, Manager for Global Product Safety and Stewardship of Rio Tinto's Copper Group, the key challenge is how to advance the risk assessment methodology to be able to get more accurate assessments and to make more efficient decisions on how to manage risks.

"So far, the protection goal for soil has been quite broad in focus, but we have now agreed to define more specific protection goals based on eco-system services. But what does this mean? For example, agricultural soil has different functions than forest soil – do we want to set the same protection goals or not? This discussion will now need to progress."

Responding to regulatory data needs is important to *Aaron Redman*, Environmental Scientist at US company ExxonMobil. "Because the chemicals that we work with span such a wide variety of physio-chemical properties, we need to provide data that is useful for the regulators and really characterises the risks that we are aiming to control."

For him, taking part in the global event brings clear synergies: "Bringing together experts who represent regulators, industry, academia and other stakeholders helps us to share ideas and find consistencies in our methodologies. It has also helped to better understand the current challenges from the regulator's point of view: what is the direction they are heading and what are the uncertainties on the way. Where we might have data, we can share it to advance the risk assessment process."

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From the left: José Tarazona, Ilse Schoeters and Aaron Redman.

NEXT STEPS

Many areas for further collaboration were identified during the workshop.

"We have been able to identify several elements where we could harmonise the scientific assessments for pesticides, biocides and industrial chemicals under REACH," Dr Tarazona says.

Dr Schoeters agrees: "It is time now to harmonise some of these aspects. Having a platform where experts from different fields can come together to exchange best practice is very important to advance the science of risk assessment so that we can make better decisions. The overall aim is more sustainable use of the soil."

"Another area where we can increase the cooperation is combining exposure assessment (how the chemicals enter into and behave in the soil) with effect assessment (how the chemicals then affect different organisms)," Dr Tarazona adds.

SOIL WORKSHOP

The workshop provided a platform to discuss and identify ways to improve international approaches in soil risk assessment and to harmonise them in different European regulations. The focus was on industrial chemicals, biocides and pesticides.

The participants represented industry, academia, regulators and other stakeholders from Europe and across the world. The event was organised jointly by ECHA and the European Food Safety Authority (EFSA) on 7 and 8 October 2015 .

SPECIFIC PROTECTION GOALS AND GUIDANCE

One of the concrete outcomes of the workshop is the agreement to define specific protection goals for soil.

"In EFSA, we have developed the idea of using eco-system services - the services that eco-systems offer to humans - to set up specific protection goals that are then used for assessing the effects of chemicals," Dr Tarazona says.

The workshop will also serve as a basis for guidance development in the implementation of REACH, the Biocidal Products Regulation and the Plant Protection Regulation (PPR). EFSA is working on revising the relevant guidance and the workshop inputs will be taken on board.

The workshop proceedings will be published in early 2016.

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ECHA's next scientific workshop, in April 2016, will focus on new approach methodologies in regulatory science.

Have a look at the video interviews with José Tarazona and Ilse Shoeters.
https://youtu.be/zvGyVJVoJII

Further information:

Workshop presentations, a video recording, background material and case studies are available on the event web page.
http://echa.europa.eu/news-and-events/events/event-details/-/journal_content/56_INSTANCE_DR2i/title/topical-scientific-workshop-on-soil-risk-assessment

2015 - INTERNATIONAL YEAR OF SOILS

The UN General Assembly declared 2015 to be the International Year of Soils to increase awareness of the importance of soil for food security and essential eco-system functions. Healthy soils are the basis for healthy food production. Soil is a non-renewable resource; its preservation is essential for food security and our sustainable future.

Further information about the International Year of Soils
http://www.fao.org/soils-2015/en/