5 Safer textiles – talking to Italian SMEs and H&M

Chemicals legislation and increased consumer demand are driving innovation in the textiles sector. We talked with representatives of a group of textile SMEs from Italy and the second largest global clothing retailer H&M, to find out how they work to produce safer textiles.

8 Need direction? Use a map

Anyone using chemical substances and products needs to know how to use them safely. But how can we manage the increase in information generated by REACH? Three sector organisations tell about the use maps they have developed for their sectors and the benefits both for registrants and downstream users.

16 Guest column: Sharing data – why is it so hard?

Alex Paul from The REACH Centre explains what companies should do to reach a fair, transparent and non-discriminatory data-sharing agreement.

20 2018 – the end of the beginning on chemicals

Think ahead to the summer of 2018 or 19 or 20. Do you know what you will be doing? We are planning ahead and thinking about how we can improve and use the data generated by REACH on chemicals.

Last push to raise awareness about REACH 2018

Happy new year to you! This opportunity to address you at the start of 2017 is bittersweet for me. Bitter, because as you may know, this is the last year that I will be working with you to deliver on the important objectives of the EU chemicals legislation. But it’s sweet too, because this is going to be an important year as we enter the final phase before the REACH 2018 registration deadline and we take the opportunity to celebrate the first 10 years of REACH.

The last 13 years of my working life have been devoted to improving the protection of human health and the environment by better understanding the impact of chemicals. Of course, I am not alone in having done that! Many of you have been doing the same – and some of you for even longer! I hope that, as well as building the intensity of our efforts this year, you can take a step back and take some pride in how far we have come together. We can be proud of what we have achieved and the impact we have had on making Europe a safer place, but we also need to make sure that we are honest about where we can improve, learn from it and build for the future. With that in mind, we are planning two conferences in Helsinki this summer. One is for key political players and the Member States to take stock and look to the future, and the other is for judges and the legal profession, to take stock of the impact of our Board of Appeal – which is a unique body within the EU, and an experience to be learned from.

Looking ahead, obviously the biggest push this year is for the REACH 2018 registration deadline. With the support of our stakeholders and the Member States, we
have some excellent material on our website in 23 languages to help inexperienced companies. And you can play a role in making sure they find it. Please reflect for a moment – is there anything more that you can do to alert companies about their obligations? Perhaps by forwarding one of our social media posts to your contacts, or by adding a couple of slides to a presentation you make, or by including a mention in correspondence with your supply chain? There’s a tool kit that you can use on our website https://echa.europa.eu/reach-2018 to help you.

We would be very grateful – but more importantly, the companies themselves will appreciate you alerting them to this important deadline and enabling them to stay in business.

Apart from the challenge of reaching smaller and inexperienced companies, the other big challenge I see is the lack of data on the impact of these smaller volume chemicals on human health and the environment. The data required by REACH on these low volume chemicals is less, but data on their impact still needs to be provided. Thankfully, there are now a variety of ways in which companies can estimate the likely effect of their chemicals without testing on animals. Please help us to direct companies to the material available here: https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals.

Thank you for helping us to reach the companies that need to know. I wish you a successful year and I look forward to seeing you in 2017.
Taking action on registrations

ECHA is making sure that registrations are up to the expected standard. If you have already registered and suspect that your dossier could be improved, don’t wait to get a letter from us – get your dossier in order.

ECHA is doing three things with existing registrations. First, we are applying the enhanced completeness check to make sure they contain the information that the law requires. Second, we are making sure that companies who have registered the same substance have just one joint registration. Third, we are taking action where companies have taken on the role of lead registrant without the agreement of the other members of the substance information exchange forum (SIEF).

REGISTRATIONS MUST BE COMPLETE

ECHA launched the enhanced completeness check on 21 June 2016. It has since been applied automatically to all new and updated dossiers. But in the interest of fairness, we are also checking in more detail the completeness of existing registration dossiers.

Last July, we wrote to companies who had provided data waivers for hazard data stating that the study was not ready. In total, we requested information for more than 140 endpoints from 39 registrations for 24 substances.

By the November deadline, almost all of the registrations (37 out of 39) had been updated. Registration decisions for the two registrations that were not updated have been revoked. This means that these companies can no longer legally manufacture or import the substances in the European Union.

We are going to continue using this approach to make sure that registrations contain the data required by REACH.

ONE SUBSTANCE, ONE REGISTRATION

Companies who register the same substance must do it jointly. This was reinforced by the European Commission’s Implementing Regulation on joint submission of data and data sharing. We are now pushing companies who breached this obligation when submitting their dossiers to correct their situation as soon as possible. We are checking companies that:

- registered individually even though a joint submission for the same substance and registration type exists;
- registered the same substance individually without forming any joint submission; and
- have formed multiple joint submissions for the same substance.

By mid-February, we had written to 188 individual registrants covering 59 substances. Because submitting jointly is a collective obligation of all registrants of the same substance, letters were also sent to those registrants that are part of the joint registration – increasing the number of companies addressed to about 2,800. The first deadline for individual registrants to join the existing joint submission is May 2017. If they do not, their registration decisions will be revoked.

We are currently looking into dossiers for substances that are registered for general purposes (i.e. non-intermediates), and expect to have contacted all registrants breaching the joint submission obligation by summer 2017.

The new REACH-IT – in place since June 2016 – does not allow dossiers to be submitted individually if a registration for the same substance and same registration type already exists.
also received letters saying that their registration decisions will be revoked unless they update their dossiers with the missing information.

HOW YOU CAN HELP YOURSELF

• Have you included all the necessary information in your dossier? Check it with the IUCLID Validation assistant. Remember that ECHA staff will also do a further manual check to see that your data is relevant within the context of REACH. These manual checks apply equally to initial registrations and updates and cannot be replicated by the Validation assistant. More information and tips are available on ECHA’s website: https://echa.europa.eu/documents/10162/13652/manual_completeness_check_en.pdf

• Is your registration up-to-date? Have you generated new information or made changes, for example, in your substance’s composition or its uses? If you have, update your registration as soon as possible with accurate data.


• Keep in mind that the SIEF members need to agree who the lead registrant is – it is not automatically the company submitting first.

ENHANCED COMPLETENESS CHECK

Based on experience since the start of REACH, and the Board of Appeal’s decision on 15 March 2016 (A-022-2013), ECHA revised its completeness check process. We started the enhanced completeness check on 21 June 2016. It improves how ECHA makes sure that all the required elements are included in the registration dossier and that the submitted information is relevant under REACH.

It applies equally to new registrations and updates. It includes additional manual checks by ECHA staff, where completeness cannot be verified automatically by using the IUCLID Validation assistant. Read more about enhanced completeness check and get advice on preparing your registration.

If we find that your dossier is missing information, you will get four months to provide it.

• An agreed lead registrant

We have been told that some companies have taken on the lead registrant role and submitted joint registrations without having agreed either their leadership or the dossier content with the SIEF members. This is not what REACH demands.

We have written to four companies who have taken the lead without agreement. Their registrations cover 54 substances. We also wrote to all the pre-registrants of the substances in question asking them to give us evidence on how they agreed to the lead registrant. If the agreed lead registrant is not the company in question, we will transfer the joint submission to the agreed lead registrant.

We are currently taking action on eight of these registrations and will soon transfer the lead role. The companies concerned will receive a letter from us. For the other registrations, we have not received evidence from the SIEF members that there is an agreed lead registrant in place.

Our checks also reveal that most of the endpoints in these dossiers were filled with placeholders instead of actual data. So, the registrants of these dossiers have

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• Is your registration up-to-date? Have you generated new information or made changes, for example, in your substance’s composition or its uses? If you have, update your registration as soon as possible with accurate data.


• Keep in mind that the SIEF members need to agree who the lead registrant is – it is not automatically the company submitting first.
• If you think the lead registration has been submitted by a lead registrant that the members did not agree on, let us know through ECHA Helpdesk: https://echa.europa.eu/contact

If ECHA asks you to confirm who is the agreed lead registrant of a joint submission, please respond.

• Be proactive and resolve issues on joint submission with your co-registrants before ECHA contacts you. You can find all the other registrants for your substance in the Co-registrants page in REACH-IT. Being proactive will give you more time to discuss and share data and agree on forming a joint submission.

• If you do not succeed in negotiating access to a joint submission or sharing data, you can, as a last resort, file a dispute with ECHA.

Further information:

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

Joint submission

Working together with your co-registrants
https://echa.europa.eu/support/registration/working-together

Disputes in practice

Ensure that your lead registrant is a responsible operator, 22 February 2016
https://echa.europa.eu/view-article/-/journal_content/title/be-aware-of-false-invitations-check-that-the-lead-registrant-is-credible

Registrants of the same substance must be part of the same registration, 25 January 2016

ECHA to review completeness of registrations, 8 April 2016

Decision A-022-2013 of the Board of Appeal, 15 March 2016

Multilingual explanations of terms
https://echa-term.echa.europa.eu/

Safer textiles – talking to Italian SMEs and H&M

INTERVIEW BY ADAM EL WAN

The chemicals legislation and increased consumer demand are driving innovation in the textiles sector. We talked with representatives of a group of textile SMEs from Italy and the second largest global clothing retailer H&M, to find out how they work to produce safer textiles.

IF YOU WANT TO GO FAR, GO TOGETHER

Making fundamental changes to your business can be a daunting task. Especially if you are a small company working within a complex supply chain. To make textiles safer or produce them with chemicals that are less hazardous, 27 Italian textile companies came together to join Greenpeace’s Detox commitment campaign in 2016. They are all from Prato, in Tuscany, Italy which is the largest textile district in Europe. The companies have different specialities, from dyes to yarn and fabric finishing, often supplying large European brands.

The Detox commitment challenges companies to eliminate harmful chemicals from their entire supply chain by 2020. “To achieve such an ambitious goal, it is essential to establish new ways of cooperating between manufacturing companies and chemical producers, and to exchange as much information as possible,” says Mr Andrea Cavicchi, President of the Italian Consortium for Detox Implementing (CID) and Confindustria Toscana Nord (CTN).

One of the Detox campaign’s goals is to remove polyfluorinated compounds (PFCs) from supply chains. Many of them are environmentally hazardous substances that are persistent and bioaccumulate in the environment as well as being linked with serious negative effects on human health. According to Mr Andrea Franchi, Chemicals Division Manager at the Buzzi Lab (a specialised laboratory carrying out testing for the textile companies in the Prato
district) seven of the Prato companies used processing techniques in which PFCs are involved. They joined forces to reduce PFCs from their production.

“Those with wet processes analysed input and output water. Those producing water repellent articles using the substitute for PFC analysed their finished product to ensure that PFC was absent. They also tested the performance of the non-PFC product against PFC-based articles. Learning from all of this, the companies are still working together to improve the performance of non-PFC-based articles. All data are shared and available for other Detox committed companies,” Mr Franchi explains.

COORDINATION

For small companies, help from industrial federations is very important. “Everyone has received support from the industrial federation CTN and, since July 2016, from the CID. This has allowed them to benefit from ongoing research and development projects that help to increase the efficiency of the production processes and promote sustainability. CTN has also offered them important technical support and helped to organise meetings between manufacturing companies, chemical producers and different international organisations that are involved in environmental safety for the textile and fashion market,” Mr Cavicchi tells.

DOES LEGISLATION HELP INNOVATION?

The global textile chain H&M has also signed the Detox commitment. According to Ms Ylva Weissbach, Sustainability Business Expert from H&M, the company has been working actively to restrict the use of hazardous chemicals in their products also before joining the Detox commitment. This applies for example to nonylphenol ethoxylates, which are toxic to aquatic life. “We started restricting nonylphenol ethoxylates in 1999 and since 2007 we have applied the limit of 100 ppm that will become the legal limit in the EU in 2021. This year we have enforced an even stricter limit as a step further towards zero discharge.”

In addition to more voluntary initiatives, she recognises the need for stronger regulation of chemicals in the EU. “Chemicals legislation, such as REACH, help us to strengthen our work to replace harmful chemicals, putting a clear demand on better chemicals management and raising awareness in the whole supply chain,” Ms Weissbach says and continues, “since we share suppliers with many other companies, it also helps us to avoid contamination since the same rules apply to all the brands.”

H&M have set up an entire infrastructure to support companies in their supply chain. They have an office in place in most countries where they produce, each housing chemical experts focusing on the final products, discharge and working conditions. “These teams are crucial in communicating with our suppliers and giving them training and support when needed,” she emphasises.

Ms Weissbach explains that the work on safer textiles is continuous and improvements happen regularly. “We are currently reviewing the process of how we evaluate chemical information, for example received in safety data sheets, to ensure that the substances used are safe. Our aim is to introduce a new method involving third party assessment.”

HELP IS AVAILABLE

Legislation and voluntary initiatives from non-governmental organisations both push companies to innovate, and there are many different tools and databases that can help find safer alternatives.

Ms Weissbach mentions ChemSec’s SIN List and SINimilarity tool as useful sources. The SIN List aims to identify substances that can be problematic before they are potentially placed under regulatory scrutiny. The SINimilarity tool allows you to compare potential alternative substances to avoid replacing one bad substance with another. In addition to these tools, Ms Weissbach recommends companies to consult scientific reports and keep up-to-date with the latest legislation to stay one-step ahead.

Since finding safer alternatives can be time consuming, Ms Weissbach suggests taking a stepwise approach. “When we phased out PFCs, for example, we didn’t do it all in one go. We started in 2009 with the winter overalls in our children’s range and then enforced a ban in our whole range in 2013.”
Prato

• Largest textile district in Europe.
• The region exports over EUR 2.5 billion of clothing annually for global brands including Burberry, Prada, Valentino, Armani, and Gucci.
• According to Greenpeace, the agreement covering the 27 Prato companies is reported to affect over 15 000 tonnes of yarn and raw materials as well as over 24 million metres of fabric every year.

H&M group

• Second largest global clothing retailer.
• Founded in 1947 in Sweden.
• Has six fashion brands and more than 4 300 stores in 64 markets.
• According to a 2016 report from Greenpeace, H&M are among the top three companies that have made the most progress in eliminating harmful chemicals from their supply chains.

Further information:

Webinar: Replacing harmful chemicals in the textiles sector

Substituting hazardous chemicals
https://echa.europa.eu/regulations/substituting-hazardous-chemicals

ChemSec business tools
http://chemsec.org/business-tool

Multilingual explanations of terms
https://echa-term.echa.europa.eu/

Sources: Greenpeace and H&M.
Need direction? Use a map

INTERVIEW BY PAUL TROUTH

Anyone using chemical substances and products needs to know how to use them safely. But how can we manage the increase in information generated by REACH? We spoke to three sector organisations to learn more about the use maps they have developed for their sectors and the benefits for registrants and downstream users.

WHAT IS A USE MAP?

The clue is in the name – it’s a map of the most common ways in which chemical products are used in a particular sector. Why is that important? Because companies need to know how their chemicals are going to be used so they can check they are being used safely. And, downstream users need guidance from companies on how they can be used safely. This communication flow up and down the supply chain is made much easier if you have a standardised use map.

The use map package helps sector organisations collect information on how the chemicals in their sector are used and provides this information in a structured and standardised way for registrants. The package contains four templates:

• One to describe the uses; and
• Three to report the information needed to assess exposure to workers (SWEDs), the environment (SpERCs) and consumers (SCEDs) for those uses.

“The use map template gives a simple overview of the most common uses in a sector and the related contributing activities. The three exposure assessment templates are linked to the use map and literally map out the specific conditions of use,” Ms Divina Gómez from the European Adhesive and Sealant Industry (FEICA) says.

WHAT PROBLEM DO THE USE MAPS SOLVE?

Formulators deal with mixtures, but the information they receive from their suppliers in the exposure scenarios is substance-related. Integrating the information is a significant challenge.

Mr Björn-Markus Sude from the Imaging and Printing Association (I&P) explains that safe use information for mixtures is an issue for the imaging and printing sector. “Information in extended safety data sheets needs to be explained in an understandable way for the end user, and with the amount of content increasing due to REACH and other legislation, this is not an easy task.”

“The exposure scenarios received by our member companies are often lengthy and difficult to manage because they have different content and different formats. This makes it difficult to analyse and consolidate the safety information to be communicated downstream to their customers. There is also an issue that they do not reflect reality as they often contain irrelevant or unrealistic operational conditions and risk management measures. We see the improved use maps as a solution for these issues,” Ms Gómez explains.

“Mixture formulators and their suppliers need to talk, but these dialogues can often be difficult when formulating construction chemicals, as they often require many substances subject to registration under REACH. This has caused considerable extra costs and effort for our members,” Mr Martin Glöckner on behalf of the European Federation of Construction Chemicals (EFCC) confirms.

The use maps were developed to overcome these difficulties.

HOW DO THE USE MAPS HELP?

By gathering information in the sector use maps, formulators can provide the data once – thereby avoiding requests from multiple companies in their supply chain.

According to Mr Sude, many of their members were receiving ad hoc use-related questions from registrants in their supply chains for substances registered. If registrants have a better description of the use, they can provide better exposure scenarios for communication and this will reduce the amount of use-related questions coming from registrants or downstream users. “With the upcoming 2018 deadline involving so many more substances, the use maps will help our members improve how they...
communicate their use of substances and mixtures much more efficiently. This is more important than ever.”

“The realistic use descriptions within the package will help registrants make their chemical safety assessment more efficiently, too. Data in the use maps will be representative for the entire sector, which should significantly reduce the communication needs of registrants and formulators. With the data in the templates provided in an electronic format (for example, in Chesar files) registrants can extract the information to use in their exposure assessment tools, eliminating the risk of errors caused when manually transferring data,” Ms Gómez explains.

“With standardised uses across an industry sector and many fixed parameters, the risk assessments should become easier and more consistent to do, although the number of uses will increase with the more detailed description. The upload of files, which are planned for the near future, will help automate the exposure assessment and this should also bring efficiency to the communication process,” Mr Glöckner says.

NEW AND IMPROVED

The use maps now describe the uses in more detail, breaking down the sector-specific uses into steps and activities and simplifies how the uses and the conditions of use are shown. This allows registrants and risk assessors to easily identify which scenarios are relevant for them, and to check for more specific details for their risk assessments in the related templates of exposure inputs.

The standardised templates give companies within the sector access to harmonised information on how the substances can be used. “For us, this standardisation is the most significant achievement. Companies within the sector and suppliers selling substances or mixtures into it now receive consistent information, in consistent formats. This allows us to communicate relevant use information to our customers in a concise and understandable form. Having information on the safe use of mixtures (SUMI) available is also a positive element that has not been available before,” tells Mr Glöckner.

The three exposure assessment templates refine the data collected on operational conditions and risk management measures according to the activity types (i.e. for workers, environment or consumers). This results in a more realistic assessment outcome as it covers actual downstream uses.

WHAT WAS THE MOST CHALLENGING PART OF DEVELOPING THE USE MAP?

“The use maps, as such, are not required by law and so this was seen as ‘voluntary’ work. We had to convince companies of the long term benefits for them,” Ms Gómez says.

Creating the use maps requires practical knowledge, expertise and a willingness to collaborate.

“We had to find a way to manage substances with different hazard profiles for the same uses, but which needed different risk management measures. To resolve this we created low, medium and high ‘risk management levels,’ which meant that different worker exposure assessments would be available for a use. This allowed registrants to react to substances with different hazard profiles,” Mr Glöckner explains.

For the imaging and printing sector, one of the biggest issues has been the wide range of uses for chemicals. “Our manufacturing and formulating process and the end uses differ greatly, making it difficult to meaningfully map the uses of the substance without becoming unclear. We tried to combine uses but this made them confusing. On the other hand, we ran the risk of adding too much detail for some activities and inputs to the exposure scenarios. So getting this balance right was not always easy,” Mr Sude says.

WHERE ARE THE USE MAPS GOING NEXT?

After their publication, the next step is to encourage registrants to use them in their chemical safety assessments. There will be events to promote and raise awareness about them amongst downstream users and registrants.
Improving safe use information of mixtures

INTERVIEW BY PÄIVI JOKINIEMI

If you produce mixtures and are struggling to put together the information on using them safely, this article is for you. There is a new approach to help you — it is called the Lead Component Identification (LCID) methodology. It has been developed to help you communicate the safe use conditions of your chemical products to downstream users and to increase the safety of those using your mixture.

REACH requires every supplier to communicate the safe use conditions for their chemical products to their downstream users. Normally, this is done through a safety data sheet (SDS). However, this is not always easy, which is where the LCID methodology can help. “It offers formulators a way of doing it based on the exposure scenarios received for a mixture’s component substances,” Dr Angelika Hanschmidt from the German Chemical Industry Association (VCI) explains.

“We hope that registrants will start to use the maps. In the medium term, cross-sector consolidation should be discussed. The idea would be for different sectors to check if they have developed similar templates for exposure to workers, the environment and consumers. If they have, the same templates could be used by different sectors. This would reduce the number used and simplify the entire process. Certain use conditions may be comparable across sectors, so this is also something we will explore,” Mr Glöckner says.

“The Adhesives and Sealant Industry will continue to work on developing ESCom phrases — standard phrases that can be used to complete an exposure scenario for communication. We will also be looking at making the exposure inputs available as Chesar files,” tells Ms Gómez. Having use maps available in a Chesar format helps the work of registrants. Chesar is an application that helps companies assess the safety of their chemicals and prepare chemical safety reports and exposure scenarios to be communicated in the supply chain.

“At the time of writing, information from five sector organisations is available in the use map library on ECHA’s website. The sector associations are A.I.S.E., Cosmetics Europe, EFCC, FEICA and I&P Europe. If you want to add your use map to the library, you can do so using a dedicated webform on our website.

Further information:

Use maps

Use maps library

Submitting a new use map

CONTROLLING THE RISKS OF THE MOST HAZARDOUS COMPONENTS

VCI and the European Chemical Industry Council (Cefic) have worked together to develop the methodology. According to Dr Hanschmidt, it provides a procedure to determine the risk driving components of the mixture. These are often the most hazardous components but also the concentration level of the substances has to be taken into account. “The safe use information
Communicating about safety of components is important for determining the appropriate operational conditions and risk management measures for the mixture as a whole. By managing the risks of the most hazardous components, the risks of the less hazardous ones are also likely to be controlled.

“Formulators of mixtures can use this methodology to derive safe use conditions for industrial, professional and consumer uses,” Dr Hanschmidt says. It is of particular relevance for mixtures that are classified according to the CLP criteria and also for those mixtures with persistent, bioaccumulative and toxic, or very persistent and very bioaccumulative components (PBT/vPvB).

**LCID – HOW TO GET STARTED?**

Cefic and VCI have a practical guide for the LCID methodology on their websites. If you have some experience in preparing exposure scenarios and safety data sheets, you should find it straightforward to use the methodology by following the guide. For specific cases, expert judgement may be needed, but the guide offers further information and examples.

As well as the guide, there is a downloadable Excel template that can help you with the calculations you need to carry out to prepare the safe use information. “Of course, if you deal with high numbers of mixtures, you are going to need a professional software solution. We are happy to see that some software developers have already implemented the LCID methodology as part of their packages,” Dr Hanschmidt says.

Although the methodology can be used for most cases, addressing both human health and environmental hazards, there are some very specific conditions where exposure or hazards change when a component is included in a mixture e.g. the corrosiveness of organic acids and amines might be lost due to a buffering mechanism of the formulation. This still requires expert judgement and is therefore out of the LCID’s scope.

**A BIG IMPROVEMENT**

Covestro, a manufacturer of high-tech polymer materials, has welcomed the methodology and made it a part of their daily operations. “We have integrated the methodology into our workflow as a standard approach for all classified mixtures that require the safety data sheet to be completed with safe use information,” says Dr Susannah Havermann, toxicologist and product safety expert from Covestro.

According to Dr Havermann, the new safety data sheets are easier to read and they focus on the most relevant information. “Using the LCID methodology has improved our safety data sheets for mixtures. Most of them have become shorter. Some annexes have become unnecessary because the safe use conditions have been embedded into the main document.”

“The methodology adds value because it efficiently connects the information from REACH exposure assessments to the current classification rules for mixtures under CLP. It uses derived no-effect levels (DNELs) and predicted no-effect concentrations (PNECs) instead of the classification alone, which allows the available hazard information to be better compared. In that way, it implements the current law and contributes to safety for the environment and the people handling the chemical products,” Dr Havermann concludes.

**Further information:**

How to identify which risk management measures to communicate for mixtures

Chemical safety report/Exposure scenario roadmap

VCI and Cefic issue a practical guide on the safe use of mixtures under REACH

Covestro
http://www.covestro.com/en

The Lead Component Identification methodology has been developed to help you communicate the safe use conditions of your chemical products to downstream users and to increase the safety of those using your mixture.
As safe as Swedish houses?

INTERVIEW BY PÄIVI JOKINIEMI

A lot of the material used in buildings contains substances that may be harmful for human health or the environment. The construction sector has a great responsibility in making sure that these substances are phased out. We spoke with Ms Marianne Hedberg from the Swedish Construction Federation to learn about what Sweden is doing to make buildings safer.

“The things we build today will still be there in 30, 50, maybe 100 year’s time. It is not enough to think about and focus on substances that we know are harmful today. In 50 years, we will know much more about all the substances used and we therefore need to have complete information now on what materials are being used in our buildings,” Ms Marianne Hedberg, Expert in environmental issues at the Swedish Construction Federation emphasises.

MAKING OUR HOMES SAFER

It is mainly the people who use buildings who are affected by harmful substances contained in building material, not the people who build them. “Phthalates have been used for many years as softeners in polyvinyl chloride (PVC) in flooring, for example. Today, we know that some of them have endocrine disrupting effects which are particularly of concern for children who crawl on the floor and breathe in dust that contains the substances,” Ms Hedberg explains.

In addition to phthalates, she mentions asbestos and polychlorinated biphenyls (PCBs) as some of the lessons that the construction industry has learnt. Today, we know that asbestos used in insulation can be a cause of lung cancer and PCB used as a sealant in the 60s and 70s has probably affected the learning ability of children who have lived in areas where it has leaked into the environment.

It requires a lot of knowledge and research to know whether a material is safe to use. According to Ms Hedberg, it is unreasonable to expect that level of knowledge from an average citizen. “We decided that the sector cannot wait for the public to demand safer materials and buildings. We need to make sure ourselves that anything we build is safe,” she says and continues, “not many people buying new houses ask questions related to construction materials. If people knew about some of the substances that can legally be used around the world to build their homes, they would definitely ask for some of them to be removed.”

FIND SAFE PRODUCTS IN THE BASTA DATABASE

The biggest construction companies, material producers, property owners and property developers in Sweden started to work together in early 2000 and established criteria to evaluate the inherent properties of building products.

The aim is to help everyone in the construction sector make conscious decisions when planning building products and to ultimately phase out the most hazardous substances from construction material.

The system that was developed is called Basta. It is a non-profit initiative owned jointly by the Swedish Environmental Research Institute and the Swedish Construction Federation. Basta is a database where material producers can register their products that meet the Basta criteria. Builders and property owners can in turn search to make sure that the materials they are considering to use are safe. The material evaluation is hazard based, which means that users need to evaluate the possible risks themselves based on their use.

The Basta criteria comply with the REACH and CLP regulations. “The only difference is for endocrine disruptors. We use the EU common EDC database for our documentation.”
tion, even though it was last updated quite some time ago. We are waiting for the new official criteria and we are in a hurry to get them,” Ms Hedberg explains.

Use of the database is free of charge, but you may need to pay a fee to register your products in the database and to attend trainings and seminars linked to the system.

SPREADING THE KNOWLEDGE

In addition to the Basta system, there are also two other initiatives – Building products assessment (Byggvarubedömningen) and Healthy house (Sunda hus) – which share the same aim of phasing out the most hazardous materials. They can be used in parallel with Basta, depending on the level of help you need and your willingness to pay for the services.

All three evaluation systems are voluntary initiatives. “These systems offer education and information on a very broad basis. They help spread knowledge among material producers and property developers and owners. The media have also started to tell people what they should be aware of and what they should ask when they, for example, consider buying a new home,” Ms Hedberg says.

PROPERTY OWNERS NEED TO DEMAND SAFE PRODUCTS

According to Ms Hedberg, the evaluation criteria and the available databases are well established in Sweden. “When a property owner orders a new house, it is very rare nowadays that they would not include any environmental demands or written criteria on how to select products.”

Although material producers are making great progress in developing safer products, it takes time. There are often good reasons for that. Since buildings are in use for a very long time, it is particularly important to make sure that new products being developed are truly safer. At the same time, they still have to have a strong technical performance.

“If we replace a hazardous material with something that is of poorer technical quality, the stability of the construction may be worse, or the lifetime of the product shorter. This can lead to a situation where you have to replace it repeatedly. This is not what we want – it is bad in terms of the life-cycle of products and is also bad for the environment,” Ms Hedberg points out.

“OUR CRITERIA ARE FREE TO USE”

Although acknowledging that the Swedish system can be further improved, Ms Hedberg is positive about the developments made to ensure the safety of construction materials. “The success factor for us has been the cooperation within the sector. We got together to figure out what could be achieved, how we could set up science-based criteria and how we could make sure that we worked in a transparent way,” she explains. In addition to the sector cooperation, the national objective of ‘a non-toxic environment’ helps keep the topic on the public agenda.

Cooperate and get started now are the two main messages she wishes to send to her colleagues all around Europe. “Our criteria are free to use and our databases contain over 100 000 products that have already been evaluated. We are keen to share our knowledge and the information we have collected,” she concludes.

Further information:

Substituting hazardous chemicals
https://echa.europa.eu/regulations/substituting-hazardous-chemicals

Basta
http://www.bastaonline.se/about-basta/about-basta/?lang=en

Building products assessment system – Byggvarubedömningen (in Swedish only)
https://www.byggvarubedomningen.se/

Healthy house – Sunda hus
https://www.sundahus.se/en/

THE SWEDISH CONSTRUCTION FEDERATION

- The Swedish Construction Federation is a trade association for private construction companies and employers.
- They focus on making the construction sector an attractive, modern and safe workplace.
- They have more than 3 100 members.

https://www.sverigesbyggindustrier.se/english

Source: The Swedish Construction Federation
Getting less harmful biocides on the market – the Danish way

INTERVIEW BY VEERA SAARI

Innovation takes time, and time is money. But what if your government was able to help you fund a project to put less harmful biocides on the EU market? This is what the Danish Environmental Protection Agency (EPA) sets out to do with a new, small-scale innovation project.

They had two objectives: to promote biocides that are less harmful to human health and the environment and to support small businesses. “From the start, we wanted to help small companies get their ideas off the ground and enter the biocides market. After running programmes to fund less harmful pesticides, and realising that small and medium-sized enterprises (SMEs) are especially challenged by the requirements of the Biocidal Products Regulation, we wanted to set up a similar scheme for biocides,” says Ms Vivi Johansen, Head of Section at the Pesticides and Gene Technology Unit in the Danish Environmental Protection Agency.

The Danish EPA decided to fund a scheme for SMEs. To be eligible for the grant, companies needed to use active biocidal substances that are considered less burdensome on human health and the environment. The scheme was part of the Danish Action Plan on Chemicals 2014-2017. In total, it gave out EUR 200 000 (DKK 1.5 million).

FINDING LESS HARMFUL OPTIONS

Biocides, by definition, kill, deter or prevent harmful organisms, such as bacteria, mould or insects. “But of course, some active biocidal substances are less harmful to our health and the environment than others,” Ms Johansen says. These are listed in Annex I to the Biocidal Products Regulation. Products that contain only these active substances are eligible for a simpler authorisation procedure and have an easier access to the markets of other EU Member States.

The grants were only given to applicants using these less harmful active substances. “This meant that the company either wanted to put a new active substance on the list of substances that are known to be less harmful, or to get an authorisation for a biocidal product that was using these Annex I substances,” Ms Johansen says.

Mr Henrik Wennermark, Ecotoxicologist at the Danish EPA, explains that the companies can use the grant to cover testing and consultancy expenses. “In their application for a new active substance, they will have to prove that their substance is stable and less harmful. In their biocidal products application, they will also have to prove that their product is effective. This requires tests and takes time,” he says.

The more substances there are on the list of less harmful active substances in the EU, the more options there are for all companies in Europe to make less harmful biocidal products. “A grant that covers costs is also important, because the data on most of the substances listed in Annex I is not protected and therefore anyone can use it to create less harmful biocides,” Ms Johansen explains.

INNOVATIVE NEW USES

Four applications were received within the two-month deadline. After careful assessment, three companies were granted funding. One company received the grant to apply for product authorisation for an in-can preservative for their paints.

Two companies received funding to get willow extract and glycerine on the EU’s list of less harmful active substances. If the substances are put on the list, they can be used as less harmful alternatives to the existing solutions to deter insects, for example.
Ms Johansen says the success ful applicants were all companies whose main business is not biocides – but who had come across a good idea with biocidal potential as part of their business. “Because their day-to-day work is focused elsewhere, they would not have had the time or the means to do the tests and put together an application. The feedback we got was that, without the grant, they would never have even pursued these alternatives.”

The results will be available in 2018 and 2019. “From now until 2019, the companies will test their substances and products, and every few months we will hear where they are with their testing and pick up the bill,” Mr Wennermark says. “We all hope that the testing will be favourable for the substances and products,” he adds.

Ms Johansen says the scheme also helped raise awareness of the EU biocides obligations. “We knew that small companies were facing challenges with biocides. People might not even know that a biocides regulation exists or that they need an authorisation to sell their products.” The Danish EPA will continue to help companies with information and guidance on the rules for approving less harmful biocides.

“We hope to repeat the scheme in the future – but this will be a political decision. Based on our experience, we would definitely recommend a similar funding scheme for any EU country, if budget permits,” she concludes.

Further information:

NO GO WITHOUT FUNDING

To be eligible for the grant, companies needed to use active biocidal substances that are considered less burdensome on human health and the environment.

Substances eligible for simplified authorisation (Annex I)

Active substances which are candidates for substitution

Danish Environmental Protection Agency
http://eng.mst.dk/

Danish Action Plan on Chemicals
http://kemikalieindsatsen.dk/english/

Multilingual explanations of terms
https://echa-term.echa.europa.eu

DID YOU KNOW?

The European Union has several support and funding schemes for SMEs in particular. Have a look at the European small business portal to find all the sources.
http://ec.europa.eu/small-business/finance/innovation-research-technology/index_en.htm

LESS HARMFUL BIOCIDES

In-can preservative for paints
The company EVD Entreprise II ApS did not want to use the common preservative methylisothiazolinone in their paints, because the substance is known to cause allergies. Instead, they are now looking to preserve their paints with a mixture based on water and sodium benzoate and propionic acid – two substances already recognised to be less harmful.

Willow extract
Ny Vraa Bioenergy I/S aims to add willow extract to the EU’s list of less harmful active substances. They grow organic willow, which they use to absorb carbon dioxide and treat wastewater from organic dairies among other things. But they noticed that willow extract could also have a useful biocidal effect.

Glycerine to fight floor dust – and ants
The company AKS2tal uses glycerine as a less chemically harmful way to fight floor dust, but now they would like to extend its purpose to fighting ants. They aim to add glycerine to the list of less harmful substances.
Guest column | Alex Paul, The REACH Centre

Sharing data – why is it so hard?

On 26 January 2016, the European Commission’s Implementing Regulation on data sharing entered into force. Together with ECHA’s new data-sharing guidance, this gave joint registrants and particularly small and medium-size enterprises (SMEs) clear instructions on what information they can expect and legally request from lead registrants. Perhaps even more importantly, it confirmed that they do not have to accept or agree to the existing data-sharing agreement if they do not believe it is ‘fair, transparent and non-discriminatory’.

LEAD REGISTRANTS GETTING BETTER

Overall, there has been a positive response to the new data-sharing requirements. Many lead registrants or consortia now provide a complete breakdown of costs after a period of time, or apologise for not yet having all the necessary information available. To allow the joint submission to progress without further delay, they highlight the reimbursement clause to allow the purchase and release of the token that the member registrants require to enable them to submit their registrations to ECHA.

HOW TO IMPROVE?

However, even a year after entry into force, it is clear that lead registrants and consortia still have some way to go to improve their cost-sharing mechanisms, justifications and response times to data-sharing enquiries. Understandably, there are situations where providing a complete breakdown of costs is challenging for the lead registrant. This could be because the registration was submitted by a third party consultant who did not adequately break down invoices, or that the registration has been transferred or sold since its original submission as far back as 2008.

Potential registrants - particularly SMEs - are often under resourced and may not be able to seek legal advice to determine if the costs for letters of access are ‘fair, transparent and non-discriminatory’. In that case, what can they do? First of all, if a lead registrant is slow in responding to a request, joint registrants should remind them that they are legally obliged to provide a full itemisation of costs ‘without undue delay’.

Once in receipt of a cost breakdown, joint registrants should assess whether they have been provided with all the necessary information, including a complete breakdown per tonnage band, of any administrative, scientific and technical costs. A reasonable justification for any additional costs such as inflation, risk premiums or advantage compensation should also be provided by the lead registrant, and joint registrants should consider if a payment for a category approach can be justified by savings made elsewhere.

When initiating the data-sharing request, applicants should present clear arguments for their request and refer to the Implementing Regulation, the latest version of ECHA’s Guidance on data sharing and ECHA’s decisions on data-sharing disputes. They should also keep a full record of any communication as this evidence will be necessary if a data-sharing dispute is taken to ECHA. This is particularly important as ECHA has found in favour of companies who have faced a lack of transparency about cost breakdowns.

HOW TO BREAK DOWN THE COSTS?

Data-sharing mechanisms and what can be considered best practice is relatively straightforward for a recent registration where a full itemisation of the technical, scientific and administrative costs are available.

All three costs should be broken down per tonnage band and for each endpoint so that registrants only pay for the data they require, while only those registering above 10 tonnes per year should pay for the chemical safety report (CSR). Set up in a spreadsheet, straightforward calculation of letter of access costs is possible, or to calculate future refunds after new members join the joint submission. Companies are reminded that they cannot negotiate an individual or reduced rate, or consider that their payment will immediately reduce data-sharing costs.

New registrants should also be made aware about potential future costs for any new testing needed – for example if the substance is evaluated as part of the Community rolling action plan (CoRAP). Registrants should understand that there is no way to legally avoid sharing the costs, even if they stop manufacturing or importing the substance. For SMEs, future liabilities running...
into tens or hundreds of thousands of euros may make the difference between a commercially successful and viable substance, or financial complications.

Dr Alex Paul joined The REACH Centre (TRC) in 2011 where he is employed as a Managing Regulatory Consultant. Alex oversees TRC’s Regulatory Services including securing, coordinating and delivering REACH and BPR services to only representative clients and industry.

The REACH Centre is a private limited company with the head office based in Lancaster, UK. It was founded in 2007 and provides chemicals regulatory management advice and compliance services to industry and government across the globe. https://www.thereachcentre.com

Further information:
- Data sharing https://echa.europa.eu/regulations/reach/registration/data-sharing
- Implementing Regulation on the Joint Submission of Data and Data sharing https://echa.europa.eu/regulations/reach/legislation

Want to know about… read-across?

If you are preparing a registration, read-across could well be an option for filling missing information. With it, you can use information from a known substance to predict the properties of another one. When used correctly, it can help you avoid unnecessary testing on vertebrate animals.

SPECIFIC EXPERTISE REQUIRED

Read-across is a complex process and you need specific (eco) toxicological expertise to do it. It is mostly used for endpoints such as reproductive toxicity, repeated dose toxicity and long-term toxicity testing on aquatic organisms and is therefore mostly relevant for high tonnage registrations. However, for the 2018 deadline, you can also use read-across for registrations above 10 tonnes for:

- screening studies on repeated/developmental toxicity;
- a repeated dose toxicity 28-day study; or
- short-term toxicity testing on aquatic organisms.

If used correctly, read-across can also reduce your costs as there is no need to test every target substance. However, developing scientifically robust predictions based on read-across takes work and ECHA has rejected the majority of cases so far because registrants have not provided sufficient justification for their predictions or enough scientific evidence to support them.

EXPLAIN, EXPLAIN, EXPLAIN

You should always explain why and how it is possible to predict the target substances’ properties. The starting point should be the structural differences and similarities between the source and the target substance.
Generic information on substances is not sufficient to make a read-across case. For example, just stating that two substances are structurally similar is not enough to predict their toxicological properties – these need to be scientifically proven.

**SHOW YOUR WORKING**

You should adequately document the scientific reasoning for any read-across. This should cover, among other things, the assumptions made and the conclusions drawn. Key data should be identified and it should include references to the substance dataset. The information needs to be substance-specific.

You need to include the supporting scientific evidence in the dossier and provide robust study summaries where possible. This is necessary so that ECHA can verify your read-across hypothesis.

**HOW ECHA ASSESSES READ-ACROSS**

To explain how the use of read-across is assessed, ECHA published a *Read-Across Assessment Framework (RAAF)* in 2015. It has now been expanded to cover environmental endpoints too.

This framework can help you to assess the quality of your own read-across. It covers REACH information requirements concerning human health, environmental fate and environmental hazards. It presents the scientific aspects that ECHA considers crucial when evaluating read-across. Hopefully, this will enable you to improve your explanations of why and how read-across can be used in your dossier.

ECHA developed the RAAF based on the most frequent types of read-across approaches used. These are written as scenarios. Each scenario is characterised by a number of scientific considerations, which are crucial to assessing read-across.

These assessment elements include questions, possible outcomes and examples. Answering these questions helps to determine whether the read-across approach is scientifically acceptable or not.

The framework does not replace the official guidance on read-across for registrants. It complements it.

Another document on read-across involving substances of unknown or variable composition, complex reaction products or biological materials (UVCBs) and multi-constituent substances is currently being drafted and will be published later this spring.

**10 TIPS FOR A GOOD READ-ACROSS**

- Make use of the QSAR Toolbox or similar tools to look for structurally similar substances.
- Provide substance identity information on all substances included in the read-across. Also, consider impurities and potentially different substance compositions when developing your argument.
- Give a hypothesis-driven justification for why the data from one substance can be used to fill the data gap for another substance. Do that for each property.
- Show how structural similarity and dissimilarity between the substances justifies your prediction.
- Create a data matrix that indicates consistency over the properties and highlights potential trends within the category.
- Analyse experimental data to confirm your hypothesis and check whether there are any contradictions.
- Justify read-across adequately and provide supporting and credible information.
- Verify that the source information you want to use for read-across complies with the REACH information requirements.
- Provide toxicokinetic information on the substances under consideration to make the read-across hypothesis more robust.
- Use the RAAF to check how robust your read-across adaptation is.

**Further information:**

- Grouping of substances and read-across

- QSAR Toolbox

- Practical guide on how to use alternatives to animal testing

- REACH 2018

- Multilingual explanations of terms
Improved QSAR Toolbox – more help for 2018 registrants

TEXT BY HANNA-KAISA TORKKELI

A new version of the QSAR Toolbox (4.0) will be launched in April. It will expand the functionalities of the tool and make it easier for you to predict the hazardousness of your substance. The update is especially targeted at new and less experienced users to help them fill in their data gaps for the REACH 2018 registration deadline.

NEW FEATURES: AUTOMATED AND STANDARDISED PREDICTIONS

You will be able to make fully automated predictions for two endpoints: skin sensitivity and short-term toxicity to fish. Just type the chemical structure of your substance in the Toolbox, select the endpoint, and the Toolbox will generate the prediction for you. The property for which you had a data gap will be filled with that predicted value. You will get the result – indicating if your substance has a certain dangerous property – in a few minutes. If the Toolbox cannot give a prediction for your substance, it will tell you.

You can also choose to use a standardised workflow on the same endpoints. This is half way between the automated prediction and the traditional way to use the Toolbox: you will get to make choices yourself at each step of the workflow, but the Toolbox will systematically highlight the best options for a meaningful prediction.

Making consistent predictions is easier with these two options. The workflow is easy to use, but an understanding of chemistry and (eco) toxicology is still needed to verify and justify the outcome.

NEW REPORT AND EXCEL TABLE FORMAT

The report that the updated Toolbox creates will be simpler to read. The most important information will be highlighted on the first pages of the report and the overall length has been decreased. You will also be able to build a customised report choosing which information to include.

Another benefit is that you no longer have to build the data matrix that you need to justify your read-across strategy manually. You can export this matrix – collecting all structures and available data – in Excel format from the Toolbox ready to be included in your IUCLID dossier. This will save you a lot of time.

IMPROVED IT

The IT system behind the software has been renewed. The improved IT makes the Toolbox more stable and faster. In addition, it is now easier to install in the servers of your company.

Further information:

QSAR Toolbox
https://www.qsartoolbox.org/

QSAR Toolbox examples

Grouping of substances and read-across

OECD QSAR TOOLBOX

- A software for grouping chemicals into categories and filling gaps in (eco)toxicity data needed for assessing hazards of chemicals.
- Can be used to fulfil REACH information requirements and assess the (eco)toxicity of substances without needing to do new tests.
- Can also help to develop integrated testing strategies.
- Has information on 66 405 substances from 47 databases.
- Currently has almost 11 000 registered users. The majority of users are from the United States, India, Germany, France and the UK. The main user group are universities and research organisations followed by the chemical industry and governmental organisations.
- Developed together by the OECD and ECHA.
- Can be downloaded free-of-charge from the QSAR Toolbox website.
Think ahead to the summer of 2018 or 19 or 20. Do you know what you will be doing? We are planning ahead and thinking about how we can improve and use the data generated by REACH on chemicals.

Remember, REACH is not over in 2018! The 2018 deadline is simply the end of the beginning. We will then, for the first time, have a better picture of the chemicals used in Europe today.

The regulatory work will continue:
• Companies still have to keep their registration dossiers up to date;
• ECHA and the Member States will continue to evaluate dossiers and substances; and
• The risks from the most dangerous substances will continue to be managed.

The amount of information freely available in ECHA’s chemicals database will continue to increase. Only a small portion of the data provided by companies is confidential.

This database is a tangible result of REACH. It provides information that will help consumers to make informed choices, improve the safety of workers and help companies and researchers to replace hazardous chemicals. This will increase the safety of chemicals worldwide as well as consumers’ confidence in their safety.

REACH AND CLP – THE KEYS TO A SUSTAINABLE WORLD

2002, the United Nations (UN) set a target aiming for the sustainable use of chemicals by 2020 and Europe is working hard to meet that. REACH and CLP are playing an important role. Together with our stakeholders, we have mapped the most important aspects that contribute to that goal.

First, is to ensure data quality. After 2018, most of the chemicals manufactured in or imported into Europe will be registered. The data is used to classify, label and use these substances safely. The key issue is that the information on chemicals is of a lower quality than expected. For industry, this hinders how efficiently they can communicate up and down their supply chains. For authorities, effective decision-making on further risk management is impeded. Therefore, improving data quality is the main challenge for sustainable chemicals.

Second, we need to manage the risks of the most dangerous substances. By 2020, we will have a lot more data on which substances are of concern and where more information is needed. This also depends on the data quality: if registration dossiers are up-to-date with correct information, it will be easier to decide which risk management route a substance should follow – for example authorisation, restriction, and harmonised classification and labelling.

Third, information needs to reach all the actors in the supply chain. This means that companies that use chemicals inform their suppliers about what they do, and in return, manufacturers and importers provide information on how to use them safely. It will also help importers and EU producers of articles to know which substances their products include – so that they can give safe use advice to their customers and promote the replacement of hazardous substances.

USING REACH DATA FOR MULTIPLE PURPOSES

The information available on chemicals on our website is increasing daily and becoming more and more reliable. It is important that we capitalise on the investment made by companies and European taxpayers. That means using the data generated by REACH for many other purposes where chemicals and their safety are important. These could cover, for example, areas where waste and water, industrial emissions, the circular economy, occupational safety and health, and plant protection products are discussed.

The aim of the UN’s World Summit on Sustainable Development (WSSD) is that “by 2020, chemicals are used and produced in ways that lead to the minimisation of significant adverse effects on human health and the environment.” This was agreed in 2002 to achieve the sound management of chemicals throughout their lifecycle.

SUCCESS FACTORS FOR REACHING THE WSSD GOAL

1. Robust data is available on all chemicals in Europe.
2. Effective regulatory risk management of the most dangerous chemicals takes place.
3. Effective communication takes place about the safe use of chemicals up and down the supply chain.
4. Information on chemicals is made freely available to citizens, businesses and regulators to help them make informed choices and increase their confidence in the safety of chemicals.

TEXT BY TIILI BRÄUTIGAM