ECHA
EUROPEAN CHEMICALS AGENCY
4 NO
September 2015

Newsletter

Authorisation – controlling risks and encouraging substitution

It has now been a little over a year since the European Commission granted its first authorisation to continue using a substance of very high concern. Since then, 10 more authorisations have been granted, the most recent ones in early September. They all authorise a specific use for a limited period of time. ECHA has also received 32 more applications and our committees have prepared 50 opinions for the European Commission. The process itself, which was introduced by REACH, is working well. This was concluded in the Conference on 'Lessons learnt on Applications for Authorisation' which took place earlier this year. http://echa.europa.eu/news-and-events/events/event-details/-/journal_content/56_INSTANCE_DR2i/title/conference-on-lessons-learned-on-applications-for-authorisation

The Authorisation List is expected to grow in early 2016. The Commission should propose additional substances to the Member States this autumn - based on both the fifth and sixth recommendations from ECHA.

Simplified authorisation

The Commission is making progress on the simplified process for applications for authorisation to use substances in low volumes. It will require less information and have a simpler application format reducing the effort that applicants need to make. Once the Commission has issued its implementing legislation, we will make the simplified formats available. Meanwhile, a task force consisting of the Commission, ECHA and the Member States continues to look for options to further streamline the process.

Chromates deadline in March

The deadline for applications for authorisation to use a group of chromium substances is in March 2016. We know that these substances are used by many companies in the EU. So far, we have received one upstream application for chromium trioxide covering several uses, two downstream applications for sodium chromates and an application for a specific use of ethylene dichloride (EDC). Altogether, we expect around 80 chromate and EDC applications covering different uses, ranging from plating for corrosion prevention in the automotive industry, to very niche uses in the healthcare sector.

To be ready to prepare opinions on the applications, the Risk Assessment and Socio-economic Analysis Committees have appointed an additional nine co-opted members to work as rapporteurs.

Downstream users – is your use covered by an authorisation?

In this newsletter, we have an article explaining the downstream users' obligation to notify ECHA if they are using a substance for which an authorisation has been granted. Remember that downstream users are covered by their supplier's application if their uses are included and the use conditions and risk management measures are followed.

The benefits of substituting SVHCs

Finally, I encourage you to take a look at our new web content and video on substitution. We have produced them with our stakeholders and on 22 September we will host a webinar explaining the benefits of substitution. We are using real case studies to show that it can be done and that it can provide business opportunities. We hope that they will inspire companies to substitute. http://echa.europa.eu/regulations/substituting-hazardous-chemicals

Jack de Bruijn
Director of Risk Management

"The Authorisation List is expected to grow in early 2016. The Commission should propose additional substances to the Member States this autumn."

Next issue of the Newsletter will be published in mid-November.

In this issue:

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ISSN: 1831-4953

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Downstream users: notify ECHA if you use an authorised substance

TEXT BY PÄIVI JOKINIEMI

Do you use a substance that is on the REACH Authorisation List? If the European Commission has granted an authorisation for the substance covering your specific use, you can still use the substance but you need to notify ECHA.

Downstream users can continue using a substance for which an authorisation is granted provided they have notifed their use to ECHA.

Substances of very high concern (SVHCs) that are on the Authorisation List (Annex XIV of REACH) can only be used after their sunset date if:

- the European Commission has granted an authorisation for the use; or
- the application for authorisation was submitted in time and the Commission's decision is pending.

An application to use an SVHC can be made by a manufacturer, importer or a downstream user of the substance. So, as a downstream user you do not necessarily need to submit an application as long as the Commission has granted an authorisation to your supplier. Naturally, you need to comply with the conditions given in the authorisation decision. These should be detailed in the safety data sheet that you receive from your supplier.

Is your substance on the Authorisation List?

Firstly, check if the substance you use needs authorisation. Currently, there are 31 substances on the Authorisation List. If it is on the list, the next thing to check is the sunset date, which is the date after which the substance cannot be used unless it is authorised.

Then you need to check if your use is authorised. If you are not sure, check the label of the product and the safety data sheet you receive from your supplier. If the substance is authorised, it will include a REACH Authorisation number 'REACH/xx/xx/x'.

The safety data sheet will contain exposure scenarios for all authorised uses. As with any other substance, your duty is to make sure that you integrate the use conditions and risk management measures described in the exposure scenarios into your work routines.

If there is no authorisation number in the product label or safety data sheet, contact your supplier. You need to understand whether your use was included in an application or they may have an alternative substance that you can use.

If your use was not included in your supplier's application and there is no alternative substance available, you either need to find an alternative solution yourself, or apply for authorisation to continue using the substance after the sunset date.

Notify within three months

If your use is covered by your supplier's authorisation, you need to inform ECHA that you are using the substance. You have three months from the first delivery you get after the authorisation decision was made.

Notify ECHA about your use through a web form on the website.

Remember that your customers may also need to notify their use to ECHA. Therefore, it is important that you pass on the information they need for their notifications.

You do not need to notify your use in the following situations:

- You have received authorisation from the Commission based on your own application;
- You are a distributor that only stores and sells the substance. However, as a distributor you need to pass on the up-to-date safety data sheets to your customers, who will need to notify their use.
- Your use of the substance does not require authorisation, for example intermediates can be used without an authorisation.

WHAT ECHA DOES WITH YOUR INFORMATION

The notifications enable the national enforcement authorities to see which companies use substances on the Authorisation List and rely on their supplier's authorisation. This helps them to see which companies have not made a notification, make them aware of the need to use the substance correctly and notify their use.

ECHA does not pass your notification to the authorisation holder but you are encouraged to do that yourself. This information will help the company (and you) later, if the company decides to apply to extend its authorisation.

ECHA has just recently published new web pages on the downstream user notification as well as the web form to notify your use.

Further information:

Submitting downstream user notification of authorised uses
http://echa.europa.eu/support/dossier-submission-tools/reach-it/downstream-user-authorised-use

Authorisation list (Annex XIV of REACH)
http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/authorisation-list

REACH-IT Industry User Manuals – Sign-up
http://echa.europa.eu/support/dossier-submission-tools/reach-it/industry-user-manuals

ECHA term
http://echa-term.echa.europa.eu/

Safety data sheets
http://echa.europa.eu/en/regulations/reach/safety-data-sheets

What to know about...REACH authorisation

TEXT BY NEDYU YASENOV

Authorisation is the "A" in REACH. It's all about making sure that the risks from hazardous substances are properly controlled and that these substances are progressively replaced by safer alternatives. Authorisation is not about banning substances, but more about guiding safe use and giving industry time to find replacement substances or technologies.

The **three-phase authorisation process** begins when an EU Member State or ECHA proposes that a chemical be identified as a substance of very high concern (SVHC). This proposal is made public in 'the registry of intentions' to give advanced notice to industry and other stakeholders.

The proposal is published online and anyone can comment on it or add further information within 45 days.

The proposal and the comments are then forwarded to ECHA's Member State Committee (MSC) to try to reach an agreement on whether it merits identification as an SVHC.

If the committee does not reach a unanimous agreement, the European Commission takes the decision. If no comments are made during the public consultation, the substance is automatically identified as an SVHC.

All SVHCs are included in **the Candidate List**. Being on the Candidate List brings legal obligations for companies manufacturing, importing or using the substance on their own, in mixtures or in articles. For example, suppliers of Candidate List substances have to provide their customers with a safety data sheet and suppliers of articles containing Candidate List substances have to provide safe use information to their customers and, upon request, to consumers.

PRIORITISING SUBSTANCES

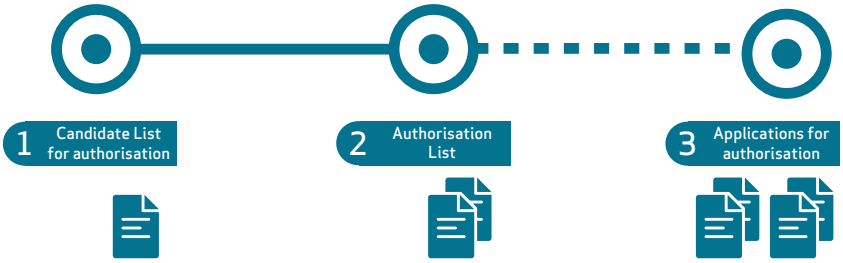
ECHA then selects substances from the Candidate List and recommends that they be included in the Authorisation List.

Priority is normally given to substances with persistent, bioaccumulative and toxic (PBT) or very persistent, very bioaccumulative (vPvB) properties, wide dispersive use or high production volumes.

ECHA usually prepares a draft recommendation, which can include several substances, once a year. It is published online and can be commented on within 90 days of its publication.

After the public consultation ends, ECHA considers the comments and updates its draft recommendation.

This updated draft recommendation will then go to the Member State Committee for its opinion. Based on the opinion of the MSC, ECHA finalises its recommendation and submits it to the European Commission. They take the final decision on which substances to include in the **Authorisation List**.



Three phases of REACH authorisation.

APPLYING FOR AUTHORISATION TO CONTINUE USING AN SVHC

A substance included in the Authorisation List cannot be manufactured or used in the EU after the 'sunset date' unless an authorisation is granted. Manufacturers, importers or downstream users can **apply for authorisation to continue using an SVHC.**

When an application is submitted, ECHA publishes information on uses applied for on its website and welcomes information on possible alternative substances or techniques for the specific uses. The consultation lasts for eight weeks.

ECHA publishes all the comments received and gives the applicants the possibility to respond publicly to the comments.

ECHA's Committees for Risk Assessment (RAC) and for Socio-Economic Analysis (SEAC) have 10 months to prepare their draft opinions. RAC assesses the risks arising from the use of the substance. This includes an assessment of the risk management measures described in the application, and if relevant, of the risks of possible alternatives.

SEAC assesses the socio-economic factors (impact on businesses, consumers and society) and the availability, suitability and technical feasibility of the alternatives included in the application.

Within three months of receiving the Committees' opinions, the European Commission prepares a draft decision on the application.

The final decision for granting (or refusing) the authorisation is published in the EU's Official Journal. The decision is subject to a time-limited review period. If authorisation is granted, companies have to comply with the obligations in the Commission's decision, such as implementing conditions or notifying ECHA of their use of the substance.

INSPIRING SUBSTITUTION

The authorisation process encourages companies to search for safer alternatives to SVHCs. Substitution requires a thorough assessment of the entire production chain and an analysis of viable alternatives as well as research into the already available resources and tools. The actual decision to start using alternative substances or techniques can only be taken by the companies directly involved in the supply chain.

Companies seem to be replacing SVHCs with safer alternatives. For example, there are several SVHCs for which the latest application date has passed but no applications for authorisation have been submitted. This means that after the sunset date their unauthorised uses are no longer allowed within the EU.

Further information:

Authorisation:
http://echa.europa.eu/regulations/reach/authorisation

Registry of intentions:
http://echa.europa.eu/addressing-chemicals-of-concern/registry-of-intentions

Candidate List:
http://echa.europa.eu/candidate-list-table

Authorisation List (Annex XIV of REACH):
http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/authorisation-list

ECHA's web pages on substitution:
http://echa.europa.eu/regulations/substituting-hazardous-chemicals

DID YOU KNOW?

Substances of very high concern
SVHCs are, for example:

- carcinogenic, mutagenic or toxic to reproduction (CMR); or
- persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB); or
- the cause of probable serious effects to human health or the environment of an equivalent level of concern as those above. This would include, for example, endocrine disruptors.

The Candidate List currently has 163 substances. The Authorisation List has 31 substances.

Authorisation applications so far
ECHA has delivered 50 opinions on applications for authorisation to the European Commission. The Commission has issued 10 decisions:

- One for DEHP for seven years (Rolls-Royce plc.) and one for four years (Roxel (UK Rocket Motors) Ltd.);
- One for DBP for 12 years (Sasol-Huntsman GmbH & Co. KG) and two for four years (Roxel (UK Rocket Motors) Ltd.); and
- One for diarsenic trioxide for 22 months (Yara France), two for 12 years (Nordenhamer Zinkhütte GmbH and Boliden Kokkola Oy), two for seven years (Linxens France SA).

Currently, 40 authorisation decisions are pending with the Commission. There are seven substances (musk xylene, MDA, DIBP, BBP, diarsenic pentoxide, TCEP and 2,4-DNT) for which the latest application date has passed and no applications for authorisation have been submitted.

Upcoming in 2016:

Completeness check to enhance availability of information

TEXT BY HANNA-KAISA TORKKELI

In 2016, ECHA will release new versions of the IT tools used for creating (IUCLID) and submitting (REACH-IT) registrations. The main changes will be an updated completeness check process and an improved system to make sure that all registrations for the same substance are made with a single joint registration. What are these about?

Who does the updated completeness check affect?

It affects all companies submitting dossiers, both new registrations and updates.

The legal requirements do not change – we are simply reviewing the implementation of the legal requirements in the submission process. So, if you do your job well and submit a complete dossier, the improved completeness check process will have no effect on you.

What will be different?

There will be improved IUCLID formats that will help you make sure that your dossiers contain all the information required for a REACH registration.

In addition, we will complement the automated check with a manual check of those elements that cannot be checked automatically. The aim is to make sure that all the elements required by the legislation have been included in the dossier.

The completeness check process will be updated in 2016. The revised IUCLID formats will help registrants to build complete dossiers.

What does the manual check mean?

We will manually check some parts of the dossier. We will not assess the quality of information – that is the dossier evaluation - but rather make sure that data is provided where it should have been.

The aim is to pick up those registrants who just add irrelevant text to bypass an information requirement.

Will it be harder to pass the updated completeness check?

No it will not. On the contrary, we expect that the updated IUCLID formats will help you to build a complete dossier.

The IUCLID Validation Assistant plug-in is a must for all. It allows you to run most of the checks that ECHA does and correct any failures before submitting your dossier.

Why is ECHA updating the completeness check process now?

Firstly, there have been regulatory changes, for example, amendments to the REACH annexes that need to be incorporated into the IUCLID templates.

One example of this is the introduction of the extended one-generation reproductive toxicity study (EOGRTS) as the standard information requirement for reproductive toxicity under REACH (Annexes IX and X).

Secondly, we have the experience of the first two registration deadlines and know, for example, where the limitations in our automated check have been. The commitment to review the process was made already in the Multi-annual Work Programme 2014-2018 and again in the REACH 2018 Roadmap.

We have worked with industry associations and the Member States to develop our plans. And we will continue to discuss the practical implementation with them too.

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We are also tightening up on the 'one substance, one registration' principle.

How will ECHA make sure that there is only one registration per substance?

We are updating the entry point of REACH-IT so that the system only allows registrations to be submitted as part of an existing joint submission or as a lead dossier.

Submitting outside a joint submission will not be possible.

However, you will still be able to submit data as an opt-out. For example, if you have disagreements with your co-registrants about the data, you can submit parts or all of the data on your own. But you still need to be part of a joint registration. In this case, you would not need to share the cost ofthe data for which you have opted out, but still be part of the same registration.

Why is ECHA taking firmer action on this?

Ensuring that companies submit their registration jointly is one of the main principles of REACH.

We want to make sure that submitting outside a joint registration is not allowed. 'One substance, one registration' minimises costs for industry, makes best use of the information and reduces animal testing.

There have also been concerns on the quality of data submitted outside joint registrations and on intellectual property right issues.

Some registrants, for example, may not have wanted to take part in the substance information exchange forum (SIEF) but instead submitted some other data on their own.

Further examples are cases where a registrant refers to data without the consent of the data owner.

In addition, the Implementing Regulation on Data Sharing, which is being prepared in the European Commission, will reinforce ECHA's role in making sure that there are no multiple registrations for one substance.

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Read more about the updated registration process in the upcoming issues of the ECHA Newsletter.

DID YOU KNOW?

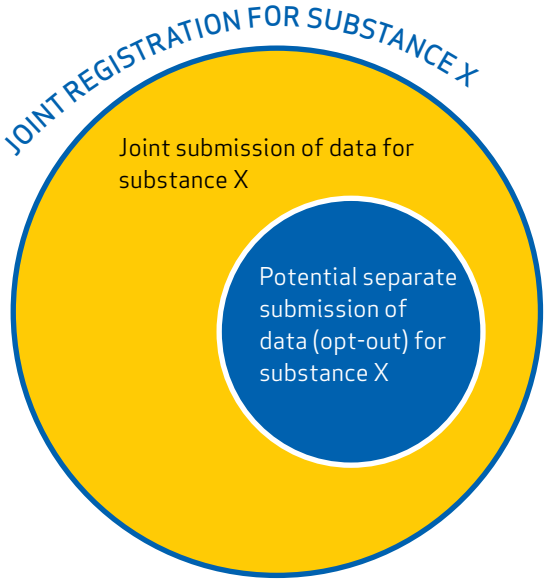
Completeness check

ECHA performs a completeness check to ensure that all the information required for registration has been provided, and that the registration fee is paid before the registration number is issued. During the completeness check, ECHA does not assess the quality or adequacy of the data submitted.

Joint registration

A registration dossier must be submitted jointly when the same substance is manufactured or imported by more than one company.

Registrants are required to jointly submit information on the hazardous properties of the substance, its classification and labelling and potential testing proposals.



All submissions should be part of a joint registration even if, in certain cases, companies may submit some information separately.

REACH 2018: Find your co-registrants

INTERVIEW BY PÄIVI JOKINIEMI AND VEERA SAARI

All registrants who intend to register the same substance should join forces in a substance information exchange forum (SIEF). The SIEF shares data on the substance and registers it jointly with ECHA. *Douglas Leech*, Technical Director at the Chemical Business Association in the UK, shares his advice for first-time registrants.

Douglas Leech at ECHA's Stakeholders' Day in May 2015.

If you have pre-registered your substance, you can find the contact details of your potential co-registrants in the pre-SIEF pages of REACH-IT. Companies in the same pre-SIEF should agree on the identity of the substance and form a SIEF. Sometimes, the discussions on substance identity and sameness might reveal that you need to find other companies with whom to cooperate.

"Companies in a SIEF may realise that they are talking about three different chemicals, not one. You can also only get access to the pre-SIEF information if you have already pre-registered your substance," Mr Leech says and adds, "therefore, if you have a chemical and you are not sure how to find your co-registrants, our advice is to contact ECHA with an 'inquiry' quoting the CAS number of your substance. ECHA will then put you in contact with the right lead registrant for your substance".

For general support in the registration process, you can get help from ECHA and the national trade associations.

"They understand your sector and the legal aspects in your country. The national helpdesks also provide practical advice and have a good idea of the issues involved. ECHA's website is a key source of information," Mr Leech points out.

JOINT REGISTRATION IS AN ADVANTAGE

Mr Leech sees the joint registration process as an advantage for small businesses.

"The primary driver for the REACH principle of 'one substance, one registration' was to help small businesses, so that they are not left alone to compete against companies that have lots of resources and data to use," he says.

Joint registration is also a way to pool resources: "Many heads are always better than one – you may not know everything and the other companies might not either, but when you put your heads together you know almost everything."

Sharing data and submitting jointly also aims to minimise the tests, resources, effort and cost needed to register.

"This is the key to the whole thing. Registration is a common goal: you all want to get your registration so that you can continue to sell your chemical, so why not work together to get it done," Mr Leech stresses.

CAN A SMALL BUSINESS TAKE THE LEAD?

One of the members of a SIEF takes the lead and submits a lead dossier – which the other members will then follow. Who should take the lead role?

One factor is who has the most data on the substance. "The companies with the most data will understand the product best and perhaps be the ideal people to be in the lead," Mr Leech says, and adds "competence and familiarity with the IT-software for registering is definitely not to be underestimated, as well as workload: do you have the time to take on the administrative and project management role of a lead registrant?"

Another factor is competition law: "You may be sitting in a room with 20 or 30 of your direct competitors and you have to be careful that you don't step over the boundaries of competition compliance".

Mr Leech also encourages companies to assess the criticality of their substance. "Is the substance absolutely vital to your business? If it is, then you may want to think about taking the lead role because you need to make sure that it gets registered".

According to Mr Leech, small businesses can take the lead registrant role. It will, however, be a lot of work.

"It may be that you will actually have to bring in a consultant or other temporary staff to do certain parts of the work."

DO YOU NEED EXPERT HELP?

Many smaller companies wonder whether they will need to hire a consultant to manage their registration.

Mr Leech says that this is, in the end, a company decision – but it is one that needs to be made quickly.

"I have talked to a number of companies who need to decide whether they have the knowledge and ability to be able to handle the registration. Competence is a key factor. Do you feel confident that you are are able to prepare your registration? If you are going to hire a consultant, do it quickly because there is a limited pool of competent consultants, and time is short."

DOUGLAS LEECH'S KEY FACTORS FOR SUCCESSFUL REGISTRATION

Knowledge. To register, you need to be an 'intelligent customer': understand what you are doing and know what it is that you are after.

Cost-awareness. REACH registration costs aren't bad – they are often the tip of the iceberg. What can be costly is the time of a consultant to handle the registration. Some of the letters to access data can also be very expensive.

Availability of consultants and test laboratories. If you need a consultant, hire one quickly, because there is a limited pool of competent experts. Some of your substances may also need tests and, for instance, even though a standard test might only take half an hour, scheduling it could take days or weeks. If you've got a lot of tests to do, this can take time.

CHEMICAL BUSINESS ASSOCIATION (CBA)

CBA represents the chemical supply chain in the UK. It advocates for a wide range of businesses – from distributors and traders to manufacturers and blenders as well as logistics and service providers. The majority of CBA members are small or medium-sized enterprises.

http://www.chemical.org.uk/home.aspx

Further information:

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

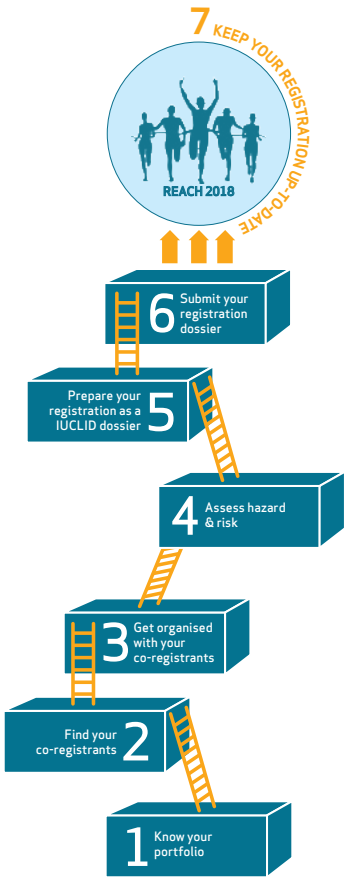
Registration support:
http://echa.europa.eu/support/registration

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

Checklist to hire a consultant:
http://echa.europa.eu/documents/10162/13559/dcg_consultant_checklist_en.pdf

Registration - regulatory information:
http://echa.europa.eu/regulations/reach/registration



Seven phases of REACH 2018

Know your rights when negotiating for data

TEXT BY HANNA-KAISA TORKKELI

Sharing data for a joint REACH registration is not always straightforward. It requires negotiating for access to data in an existing registration dossier or with companies preparing a new one. To help potential registrants in their data-sharing negotiations with existing registrants, ECHA published practical advice on its website in May. ECHA Newsletter spoke with *Mr Daniel Sompolski*, from ECHA's Substance Identification and Data Sharing Unit, to find out more about how small and medium-sized companies (SMEs) can succeed in their negotiations.

The key principle of data sharing is that all companies registering the same substance should share data and its costs 'in a fair, transparent and non-discriminatory way'.

Data sharing is not meant to generate profit for the data owner but rather to share the costs of studies and the related administrative work between all co-registrants.

"What is fair, transparent and non-discriminatory is always case-specific. If you feel that the price of registration is too high, it does not necessarily mean that it is against these principles. In some cases, generating data can indeed be very expensive," says Mr Sompolski and continues, "You need to be able to objectively challenge the price with valid arguments if you feel that the principles have not been followed properly."

According to Mr Sompolski, no one should be afraid of data-sharing negotiations – everyone can do it. "You don't need a lawyer, just common sense and the same skills you have to run your business negotiations."

BE CRITICAL AND ONLY PAY FOR THE DATA YOU NEED

Sharing data requires cooperation between companies, who might operate in the same market and even be competitors. This is another thing that should be taken into account in the negotiations. "You should always critically assess what you are being offered."

Companies should not be afraid of data-sharing negotiations, says Daniel Sompolski.

Although companies do not need external help to figure out the cost breakdown, they might need help from an expert to assess the quality and usefulness of the data.

"There might be a need for expert support in defining what information is needed specifically for your substance and use. Doing this could also save money as you then don't pay for access to information you don't need," Mr Sompolski explains.

ECHA CAN HELP WITH DISPUTES

Companies should make every effort to come to an agreement on sharing data and submit a joint registration. However, if the negotiations fail, ECHA can help to resolve a dispute.

ECHA's dispute process is free-of charge and requires no legal support. "We have published all our dispute decisions online, so anyone can see how ECHA assesses the cases," Mr Sompolski highlights. Since 2010, ECHA has resolved 30 disputes, 13 of which have been in favour of the potential registrant.

If the ECHA decision is not favourable, it usually means that not all efforts have been made to reach an agreement. In such cases, co-registrants must continue negotiations and pay attention to the advice given by ECHA.

"It should, however, be kept in mind that most substance information exchange forums (SIEFs) have and will continue to work very well, respecting the spirit of REACH," Mr Sompolski concludes.

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To succeed in data-sharing negotiations, have a look at ECHA's website. There is also information about the different cost elements that you may encounter during your negotiations and advice on how to overcome difficult situations and carry on negotiating: http://echa.europa.eu/regulations/reach/registration/data-sharing/practical-advice-for-data-sharing-negotiations

Further information:

Factsheet on typical cost elements in data-sharing negotiations: http://echa.europa.eu/documents/10162/13631/factsheet_costs_datasharing_en.pdf

Data-sharing dispute decisions: http://echa.europa.eu/regulations/reach/registration/data-sharing/data-sharing-disputes/echa-decisions-on-data-sharing-disputes-under-reach

IMPLEMENTING REGULATION TO STRENGTHEN THE POSITION OF SMES

The European Commission is currently working on an Implementing Regulation on Data-Sharing in REACH. It is under consultation with industry associations and Member States at present and expected to enter into force in early 2016.

The Commission's proposal is based on past experience with data sharing. It will regulate more clearly how potential and existing registrants interact. The new rules are expected to help SMEs cope with the costs of REACH compliance.

Substance identification needs strong analytical data

TEXT BY HANNA-KAISA TORKKELI

Good quality analytical data is essential to accurately identify your substance. This applies whether you are registering in a joint submission under REACH or inquiring about your substance to find your potential co-registrants. Good quality means that your data fulfils the legal requirements and is specific enough for ECHA to be confident about the identity of your substance.

© FOTOLIA

Substance identification is at the core of the chemicals legislation. The analytical data in dossiers should be consistent and sufficient for an accurate identification of the substance.

Under REACH, a substance is identified by its chemical name and other identifiers, as well as its composition. Analytical data is used to determine the composition.

The analytical data in your dossier should be sufficient to confirm the composition of your substance – keeping in mind that ECHA's experts who review this data may not have an intimate knowledge of your substance and how it is manufactured.

The REACH Regulation lays down the legal requirements. If you manufacture organic substances, you should conduct a set of spectral analyses, such as ultraviolet (UV), infrared (IR) and nuclear magnetic resonance spectroscopy (NMR) as well as a chromatographic analysis such as gas or liquid chromatography.

If you manufacture inorganic substances, you may need to use other analyses, as the techniques specified in the REACH Regulation are more suited to organic substances.

GETTING THE DATA

The testing of your substance and the interpretation of the test results may be difficult and cost-intensive **if you have complex substances or if you are not sure what you have**.

In this case, you may need help from an external service provider, who can analyse your substance and confirm its identity. Remember to reserve enough time for this.

If you import a substance, particularly as part of a mixture, you may not have the necessary data to hand. In such a case, you should ask your supplier for information on the identity of the substance, including its composition and analytical data. However, if you cannot get the information, you will need to organise the analysis yourself.

GOOD KNOWLEDGE OF YOUR SUBSTANCE BENEFITS YOUR BUSINESS

Good quality data backs up your substance identity and makes sharing data for a joint registration more efficient.

This is because you are able to make robust decisions on substance sameness and to understand the relevance of the hazard data for

your substance. It also supports, for example, your justification for using read-across to assess the hazard of your substance as well as determining whether your substance needs regulatory risk management, such as harmonised classification and labelling.

All in all, accurately knowing what you manufacture or import helps you to manage your substance safely throughout the supply chain.

***

Watch the video with Dr Stuart Niven from Harlan Laboratories Ltd. about analytical data and his advice to importers.
https://www.youtube.com/watch?v=LU-lWsNH_T4

Further information:

Guidance on identification and naming of substances under REACH and CLP:
http://echa.europa.eu/guidance-documents/guidance-on-reach?panel=ident_nam_subst#ident_nam_subst

TOP TIPS ON ANALYTICAL DATA:

- Take a professional interest in your substance to know what it is.
- Ask yourself if the data you provide for the identification of your substance is clear for someone who does not have an intimate knowledge of your substance and how it is manufactured.
- Interpret the data before submitting it to enable ECHA to handle your dossier efficiently.
- Make sure that the substance identity, including composition and analytical data, provides a consistent and accurate picture of your substance.

REACH Annex VI(2):
http://echa.europa.eu/regulations/reach/legislation

Questions and answers on substance identification:
http://echa.europa.eu/qa-display/-/qadisplay/5s1R/view/reach/substanceidentification

Substance identification:
http://echa.europa.eu/regulations/reach/substance-identity

How to characterise and identify your substance:
http://echa.europa.eu/support/registration/how-to-characterise-and-identify-your-substance

ECHA term:
http://echa-term.echa.europa.eu/

Reaching out to downstream users

INTERVIEW BY PAUL TROUTH

One of ECHA's goals is to help downstream users understand their obligations under REACH. As they often belong to different industrial sectors with complex supply chains, reaching them can sometimes be a challenge. ECHA launched a project with six Member States in 2014 to target environmental, health and safety (EHS) professionals in downstream user companies throughout Europe. ECHA Newsletter spoke to *Ms Maria Letizia Polci* and *Ms Luigia Scimonelli* from the Italian REACH and CLP competent authority, to find out more about the project.

ESTABLISHING A TASKFORCE

The starting point for the Italian project was to get as many organisations as possible involved.

"We wanted to form a taskforce that would represent as many sectors as possible. This would allow our work in promoting downstream users' understanding and compliance with REACH to be as far-reaching as possible. And, actually, we managed to get new organisations on board," says Luigia Scimonelli.

"We are refocusing all our activities to meet the specific needs of downstream users in non-chemical sectors," Maria Letizia Polci explains and continues, "on the other hand, we have new initiatives in education and training, communication and information-sharing to raise downstream user awareness".

EDUCATIONAL INITIATIVES TO REACH EHS PROFESSIONALS

The competent authority began concentrating their main efforts on collaborating with EHS professionals who work as employees for companies or as consultants. In Italy, EHS professionals work, for the most part, in the field of workplace safety.

"We have a 'Responsible for Safety Protection and Prevention (RSPP)' agreement in place that outlines criteria for developing mandatory training for EHS professionals," Ms Scimonelli tells.

"There is a real need to focus the training programmes on downstream user obligations for specific economic sectors. We see our role in this as developing synergy between the many actors involved," she adds.

The authority is contacting the most relevant actors involved in delivering training for EHS professionals and to involve them in encouraging communication between companies and the REACH and CLP authority.

These actors include the REACH technical coordination committee, the Italian Advisory Committee on Safety and Health at workplaces, the inter-regional coordination bodies for REACH implementation and workplace prevention as well as the Council of scientific and professional associations.

Still in the field of training, the competent authority has worked with the Ministry of University and Research to set up Master's and specialisation courses on REACH and risk assessment and has also supported universities to set up such courses.

"We want to encourage students and graduates from these courses to participate in internship programmes in consultancy firms, industrial associations, companies and national institutions. Through this, we will be able to reach downstream users indirectly," Ms Scimonelli informs.

ACCESSING INFORMATION

To help downstream users meet their obligations, several national institutions have provided free access to databases on classified substances, carcinogens, sensitisers, banned or restricted substances relevant for REACH and environmental legislation, and safety data sheet models.

ECHA's press releases, Chesar videos and other supporting documents and tools have also been translated.

"We have a number of translations already planned for the next two years including the safety data sheet e-Guide and the downstream user interactive map. The Irish Health Service Executive's (HSE) classification and labelling tool is also being reproduced," Ms Polci says.

"We will prioritise industrial sectors that include SMEs, and carry out a targeted study to reach them and better understand their needs," she adds.

MORE SUPPORT FROM ECHA

Ms Polci believes that ECHA's project and the initiatives taken so far in Italy have had a strong impact on improving downstream users' understanding of their obligations. But, she also thinks that more could be done.

"We would love to see continued investment in reaching out to downstream users; and would like to see ECHA staging even more sector-specific meetings," Ms Polci suggests.

"It is so important to standardise terminology for duty holders to use when communicating information down the supply chain, and ECHA could play a pivotal role here by collecting the initiatives of Member States or stakeholders and making them publicly available for all," Ms Scimonelli concludes.

Further information:

Italian government web portal:
www.reach.gov.it

SDS e-Guide (in English):
http://view.pagetiger.com/ECHAe-Guide1-1/Issue1

Downstream users:
http://echa.europa.eu/regulations/reach/downstream-users

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

ECHA term:
http://echa-term.echa.europa.eu/

BACKGROUND

All companies in Europe have EHS professionals who define safety procedures and policies to help companies comply with workplace safety directives and environmental regulations. Since they are so widespread in companies throughout Europe, reaching them could be vital for raising downstream user awareness.

The 2014 project involved ECHA and the authorities in six Member States (Italy, Finland, France, Poland, Portugal and the United Kingdom) developing initiatives to reach out to downstream users.

So much information, so little space

TEXT BY HANNA-KAISA TORKKELI

Mixtures being placed on the EU market had to be reviewed by 1 June 2015 to comply with the Classification, Labelling and Packaging (CLP) Regulation. This meant, in many cases, that mixture producers had to re-classify their products and include more information on the product label than before. The increased amount of information has proven to be challenging, especially for products sold in small packages.

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Artists' colors are often sold in small packages. Adding the information required by CLP on small paint tubes can be challenging.

ColArt, the leading supplier of artists' materials in the world, had to re-classify a majority of its mixtures. "A lot of our products were classified as non-hazardous to health and the environment under the Dangerous Substances Directive/Dangerous Products Directive. Now, we had to go through the exercise of re-evaluating these products to check if they were still non-hazardous under CLP, as the classification criteria is different," says *Sara Brennan*, Global Product Safety Manager at ColArt. "As a result, a large percentage of our mixtures had to be re-labelled."

COMMUNICATING HAZARD INFORMATION AND BRAND

Making sure that the pictograms and hazard information fit on the product as well as information that the user finds useful, such as product name, colour and use, has been challenging. "Our brands are an important part of ColArt' s heritage, so it is imperative that we communicate the hazard information, but still allow our brands to be marketed appropriately on our products and packaging as well", Ms Brennan says.

In addition to CLP, some of ColArt's products need space for additional pictograms, such as Green Dot, Wheelie Bin and the tactile warning triangle. Those materials that the company sells in the US require additional certifications and logos.

"We also have some products that are classified as cosmetics and so we may have EU Cosmetic Regulation labelling to comply with as well," Ms Brennan points out.

COSTLY SOLUTIONS

ColArt have solved the issue by using peel and reveal labels, by adding an outer packaging such as a blister card, and by making use of the exemptions offered by CLP on packages smaller than 125 ml.

"The use of peel and reveal labels has been tricky and costly to implement. The label cost has increased but so has the number of personnel hours to make sure that the label is printed correctly. We have also had to make sure that there is enough room to meet the language requirements of the countries where the product is sold," Ms Brennan explains.

In some cases, her company has had to produce separate labels/packaging or language clustered labels for different areas of sales.

"This can increase the number of stock keeping units and adds increased complexity in the supply chain and for the manufacturing sites."

REDUCING LANGUAGE VERSIONS

Dr Engin Temeltaş, Head of Regulatory Affairs at Axalta Coating Systems EMEA, says his company had to re-label "nearly all of their 10 000 mixtures" used mainly in the coating of vehicles, motors, buildings and pipelines.

"The main challenge for our small packages has been the language versions. Our products in small packaging sizes are designed to be supplied to several European countries because quantities and efforts would not allow individual stock keeping units per country. Therefore, these products need to carry hazard classification in several languages," he says.

His company had to adjust the layouts of their labels.

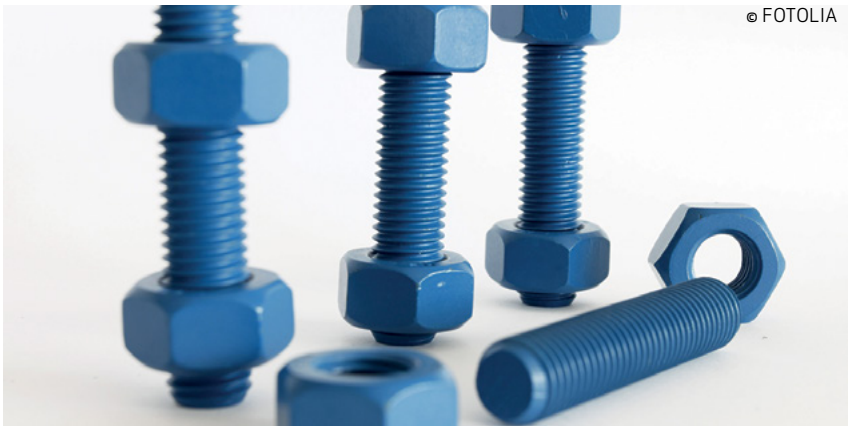
"In individual cases, we considered other solutions, such as reducing the number of languages displayed on the label, or using multifold labels."

LOOKING FOR INNOVATIVE SOLUTIONS

CEPE, the organisation representing producers of paints, printing inks and artists' colours in Europe, has been active in developing pragmatic solutions for small package labels as well as guidance on the use of such labels. The work on the guidance is still under way and will be discussed by the network of national helpdesks for REACH, CLP and biocides (Helpnet) in a workshop in September.

"Similar proposals for small package labels are also being developed in the UN Sub-Committee of Experts on the Globally Harmonised System (GHS), in which we participate as part of the International Paint and Printing Ink Council," says *Janice Robinson*, Director Product Regulations at CEPE.

The organisation publishes its own labelling guidance for members, which includes a sector-orientated tool to prioritise and reduce precautionary statements.



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Coatings industry is hugely affected by CLP.

Ms Robinson says that many of their member companies have solved the issues in ways described by Ms Brennan and Dr Temeltaş.

"However, the solutions now found are still not enough for some of the smallest packages, 50 ml and below, so we are keen to promote discussion on innovative solutions making use of modern technology. For example, using QR (Quick Response) codes and/or short URLs on the labels to allow customers to access additional information or languages online could be one option."

Further information:

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

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

ColArt:
http://www.colart.com/

Axalta Coating Systems:
www.axaltacoatingsystems.com

CEPE:
www.cepe.org

CLP - harmonising communication on hazards

The CLP Regulation aims to make sure that the hazards presented by chemicals are clearly communicated to workers and consumers in the European Union through the classification and labelling of chemicals.

Workers and end users benefit from the review of hazard classifications.

"Basically, the intention of harmonised communication on hazards is a great benefit in terms of ease to share and to understand the hazards and risk management measures of chemical products around the world," says Dr Temeltaş.

Ms Brennan agrees but adds that "with CLP having different cut off limits for the same endpoint under GHS, and countries globally having adopted different building blocks of GHS, the aim has been somewhat diluted."

"With CLP, all companies have had to revisit the hazard classification of their products. This should result in more up-to-date and accurate hazard classifications of products," Ms Brennan concludes.

CLP introduces new pictograms.

Replacing harmful chemicals – the American way

INTERVIEW BY IRENE POZA LATORRE

Replacing substances of very high concern (SVHCs) with safer alternatives plays an important role in protecting human health and the environment in the European Union. But do non-EU countries share the same aims and how do they go about it? Looking at a different approach to substitution, ECHA Newsletter spoke with Dr *Joel A. Tickner*, Director and Associate Professor of Community Health and Sustainability from the University of Massachusetts Lowell, who has experience in helping US companies find safer and suitable alternatives to chemicals of concern.

SUBSTITUTION IN EUROPE VS SUBSTITUTION IN THE UNITED STATES

The main driver for substitution in the United States is consumer and business pressure. "We see an evolving consumer who is concerned about the chemicals in the products they buy," Dr Tickner says and continues: "consequently, retailers and brands are demanding safer products from suppliers."

However, when an American company is considering substitution, the government bodies have a more involved role, particularly in Massachusetts, where the evaluation of alternatives is mandatory for manufacturers using toxic chemicals.

"We work very closely with industry on the implementation phase to make sure that substitution really happens and the toxic reduction is real. We also focus more on the process, application and implementation, while the EU approach focuses more on the outcome," Dr Tickner compares.

The US way of performing alternative assessments has been more about the hazardous properties of substances and less about exposure and risk. The Americans have also had a more prescriptive approach when guiding companies on how to substitute a substance of concern. "The public doesn't necessarily trust the industry science," says Dr Tickner. In fact, in

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Consumers are the main drivers for substitution in the US, says Dr Joel Tickner from the Univerity of Massachusetts Lowell.

the United States the assessment of alternatives has rested more with governments, while in Europe the responsibility lies primarily on industry.

DIFFERENT BUT COMPLEMENTARY

Even if the approaches to substitution are different, Europe and the United States can learn from each other. "What the United States could learn from Europe is how to design policies that enforce substitution and also how to engage companies in data collection through the supply chain to evaluate and apply alternatives," Dr Tickner highlights.

He also points out that one of the biggest barriers for substitution is poor information flow in the supply chain. "Those who are lower in the supply chain, often the retailers, don't have information on what chemicals are in their products, or they may not have the technical ability to understand what alternatives exist."

On the other hand, there are lessons that the Europeans could learn from the United States. "We have a lot of experience in developing partnerships with other organisations such as industry or NGOs to evaluate the alternatives and to implement them."

The collaborative approach is important especially for small and medium-sized companies (SMEs), who may not have the capacity or the money to adapt or do research on alternatives. "At the University, we overcome these barriers by facilitating partnerships, by carrying out collaborative research and by testing the alternatives," Dr Tickner explains.

AVOIDING REGRETTABLE SUBSTITUTION

The University of Massachusetts Lowell has been involved in assessing safer alternatives for more than 25 years – they identify, compare and help companies to select safer alternatives to chemicals of concern. There has been a significant evolution in frameworks, tools and initiatives to support "informed" substitution in recent years in the United States.

The goal is to gain and share knowledge about the advantages and disadvantages of chemical or non-chemical alternatives. "This knowledge is essential as we don't want to end up with regrettable substitution," advises Dr Tickner. "On one hand, it is important to evaluate whether there is a safer alternative, but on the other hand, you must consider how you can make it work for industry".

The University of Massachusetts Lowell collaborates with the State of Massachusetts through the Massachusetts Toxics Use Reduction Program, aiming to support local companies to find safer alternatives. This programme requires the firms that manufacture, process or use toxic chemicals in amounts over five tonnes per year, to understand how and why they are using toxic chemicals. Every two years, these companies undertake prevention planning to identify alternatives to gradually reduce the use of these chemicals.

The companies also pay a fee that funds a regulatory programme, a technical assistance programme through the Massachusetts Office of Technical Assistance, and a research and education programme on safer alternatives through the Toxics Use Reduction Institute at the University of Massachusetts Lowell.

"We at the University educate the people who will be doing the assessment and conduct research on safer alternatives to help Massachusetts companies substitute hazardous chemicals," Dr Tickner explains.

EXAMPLES OF SUBSTITUTION

According to Dr Tickner, the European regulations are also driving substitution in the United States.

For example, because the Massachusetts electronic industry exports to Europe, they had to find a suitable alternative due to the restriction of the use of lead in electronic products under the ROHS Regulation.

"Companies started a pre-competitive collaboration to identify and test the alternatives among themselves, and to work out the technical difficulties. The combination of the collaboration and the regulatory driver forced that substitution to happen."
A successful example of collaborative research and partnership with SMEs is the work carried out in the State of Massachusetts to reduce the use of trichloroethene (TCE), one of the most widely found chemicals in contaminated sites in the United States.

"We worked together with SMEs testing alternatives and helping them to take away the technological risk to substitution," says Dr Tickner.

As a result, they reduced the use of trichloroethene by 95 percent, saving industry millions of dollars. In the end, the companies were able to find alternatives that provided the function of TCE (i.e. degreasing metal parts) without the risks.

Further information:

University of Massachusetts Toxics Use Reduction Institute:
http://www.turi.org/

ECHA's web pages on substitution:
http://echa.europa.eu/regulations/substituting-hazardous-chemicals

Video on substitution:
https://www.youtube.com/watch?v=Zs8oPSXdU5U

Video interview with Dr Tickner:
https://www.youtube.com/watch?v=J--HTkavhT0

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Interstate Chemicals Clearinghouse's (IC2) Safer Alternatives Assessment Model. The Massachusetts Toxics Use Reduction Institute follows this to assess safer alternatives.

DR TICKNER'S TIPS FOR COMPANIES CONSIDERING SUBSTITUTION:

- Pre-competitive collaboration. The move towards safer chemicals is about partnerships and collaboration within your supply chain and your sector. Identify the barriers and learn the best practice from your own sector as well as from other sectors.
- Focus on the application, to identify where there is a potential pre-competitive collaboration to design, test and adapt an alternative to a chemical of concern.

Nanomaterials - new data available

INTERVIEW BY VEERA SAARI

New data on 11 commercially viable nanomaterials was made available in June as part of a seven-year testing programme by the Organisation for Economic Cooperation and Development (OECD). The information gives those companies who have registered or will register these nanomaterials in the EU, an opportunity to consider the data in their registration dossiers.

"If the information is relevant for the assessment of safe use of your substance, we encourage you to update your registration dossier to make sure the substances are used safely," says *Jenny Holmqvist*, coordinator of nano activities in ECHA and Chair of the OECD steering group on the Testing and Assessment of Manufactured Nanomaterials.

"The OECD testing programme has made it possible to release an unprecedented volume of nano-specific data to the public," says Jenny Holmqvist. The aim of the programme was firstly, to assess whether the existing test guidelines for substances need to be adapted to consider nano-specific issues, and secondly, to respond to the growing need for nano-specific data.

MORE DATA ON ITS WAY

The OECD testing programme addressed 59 endpoints for 13 nanomaterial substances that are currently, or will soon be, on the market. The work is not yet complete. "In total, the programme has generated over 700 study reports – but not all of them are available yet," Ms Holmqvist says and mentions that more data will be released in batches over the coming months. "The reason for this is that the data was generated in different formats and is currently being merged into IUCLID. All the data is currently published on the OECD website, where you can choose different ways of searching the IUCLID files. Ultimately, the data may be incorporated into the eChemPortal, together with other hazard information about chemicals," she explains.

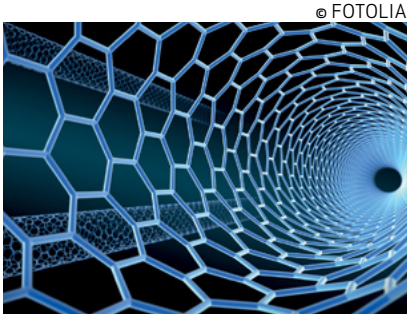
NEED FOR NANO-SPECIFIC TESTING GUIDELINES

The data available confirms that, in general, the existing test methods used for conventional substances are also applicable for nanomaterials. "It is reassuring to be able to conclude this. However, there may still be a need to look further into the details of the testing guidelines to capture the potential challenges of testing nanomaterials compared to other chemicals," Ms Holmqvist stresses. This work is currently ongoing at OECD level under the steering group chaired by ECHA.

"Many of the test guidelines have been reviewed and updated. More effort is needed still on for example specific standards, methods and protocols to allow for a proper characterisation of nanomaterials," Ms Holmqvist explains. Such methods are normally not in the battery of test guidelines, and therefore the development is spread between other international organisations, such as the International Organisation for Standardisation (ISO).

NEXT IN NANO WORK

The next step at OECD-level is the actual assessment of the nano-specific information to harvest the experience gained. "This means getting more specific information on how the tests were carried out, whether any adaptations were made, and whether there were any differences between the studied nanomaterials in the applicability of the tests done," Ms Holmqvist says. "This will add more value to the available data." The outputs will be incorporated into the ongoing revision of the OECD testing guidelines and guidance documents.



The OECD testing programme has made it possible to release a great volume of nano-specific data to the public.

The programme for ECHA's nanomaterials work for 2016-2018 will be published towards the end of 2015. "ECHA will continue to closely follow the next steps at OECD level," Ms Holmqvist mentions, "and, depending on the developments, take this into account in our operational activities, like in the compliance check of registration dossiers and guidance development."

ECHA will also be following how the release of the nano-specific data is used in REACH through new registrations and dossier updates.

NANOMATERIALS DATA

- fullerenes
- single-walled carbon nanotubes
- multi-walled carbon nanotubes
- silver
- gold
- dendrimers
- silicon dioxide
- nanoclays
- titanium dioxide
- cerium dioxide
- zinc oxide

Nanomaterials - why are they such a hot topic?

"Nanomaterials, or nanotechnology which makes use of these materials, bring great promise and solutions across the vast majority of industry sectors," Jenny Holmqvist explains.

"Nanotechnology offers smarter solutions and introduces improvements, for example, with better solar cells, more effective medicines, lighter materials and enhanced surface technology. Many amazing new solutions are still with researchers in laboratories and haven't even reached the market yet."

"But with any emerging technology, there is a balance to be struck - between the benefits and potential risks," Ms Holmqvist says.

"When it comes to emerging technologies, such as nanotechnology, legal frameworks are to some extent playing a catch-up game where the implementation of existing guidelines might have to be adapted to fit new developments." In the case of nanomaterials, a particulate substance is made into even smaller particles. "

There is no evidence that nanoparticles are toxic *per se*, but there are indications that the behaviour of those small particles at nanoscale may change compared to bigger-sized particles. The million dollar question is, of course, are those changes of relevance for the safe use of the substance?"

Further information:

Testing programme of manufactured nanomaterials:
http://www.oecd.org/chemicalsafety/nanosafety/testing-programme-manufactured-nanomaterials.htm

OECD guidelines for testing of chemicals:
http://www.oecd.org/chemicalsafety/testing/oecdguidelinesforthetestingofchemicals.htm

Nanomaterials on ECHA's website:
http://echa.europa.eu/en/regulations/nanomaterials

Chemicals in our life - nanotechnology:
http://echa.europa.eu/chemicals-in-our-life/hot-scientific-topics/nanotechnology

Chemical leasing - the way forward?

TEXT BY HANNA-KAISA TORKKELI

What if the next time you need chemicals in your company, you do not buy them but rather you pay for a specific service to do the job for you? This is the essential idea behind chemical leasing – an innovative chemicals management business model that has begun to shift the conventional practice of buying chemicals to purchasing services that chemicals provide.

Under the conventional approach, it is in the interest of chemical manufacturers and distributors to sell as much of a product as possible. This can easily lead to excess financial, environmental and potentially health-related costs and liabilities.

In the chemical leasing model, the producers/suppliers sell the functions of the chemical along with the associated specialist know-how, while the ownership of the product remains with them. So, customers are not paying for their chemicals by volume, but rather agreeing on a value-based unit of payment, such as cleaned area in square metres or coated number of bottles. In the leasing model, the supplier and customer develop a strong cooperation based on trust, exchange of experience, and gain financial as well as environmental benefits.

INITIATIVES ALREADY IN 2005

The innovative approach was introduced already in 2004 by the United Nations Industrial Development Organisation (UNIDO), together with the Government of Austria. Initiatives were first launched in developing countries - Egypt, Mexico and Russia in 2005; Sri Lanka, Serbia and Colombia in 2008 – to demonstrate the applicability of the model.

These pilot programmes were executed with businesses that ranged from potato farms to candy manufacturers and from textile dying to water bottling plants.

Since then, over 50 chemical leasing projects have been implemented all over the world. All the projects are carried out in close cooperation with the National Cleaner Production Centres (NCPCs). In many countries, chemical leasing has a central place in the chemicals policy.

At present, UNIDO is coordinating projects in Serbia, Sri Lanka, Colombia, Brazil, Croatia, Mexico, Nicaragua, Russia, Ukraine and Uganda.

The chemical leasing trend has also reached European suppliers and a number of companies supplying chemicals have started providing services. For example, the Dow Chemical Company is using the chemical leasing model to provide industrial surface cleaning services for the aerospace, automotive, electronics and other industries.

Ecolab, a global provider of water, hygiene and energy technologies

and services, has cleaned equipment at Coca Cola's bottling plant.

ENVIRONMENTAL AND BUSINESS BENEFITS

Chemical leasing projects show that replacing a product with a service has positive environmental benefits, for example, by reducing harmful emissions and decreasing the amount of waste.

Chemical leasing also enhances the management of chemicals by making companies think about why chemicals are being purchased and how and where they are being used. Business benefits include considerable savings, for example, by streamlining inventories and cutting down on the volume of chemicals purchased; establishing long-term partnerships based on mutual trust; and enhancing customer satisfaction and innovation.

More information about UNIDO's projects is available online:
http://www.chemicalleasing.com/sub/intact.htm

Sources:
Dr Thomas Jakl, Deputy Director General, Ministry of Environment, Austria; member of ECHA's Management Board
http://www.unido.org/chemical-leasing.html
http://www.chemicalleasing.com

"Chemical leasing should become the standard business model"

Dr Thomas Jakl, Deputy Director General at the Austrian Environment Ministry, has been involved in developing the chemical leasing model since its beginning. According to him, chemical leasing is the "only business model which makes it economically attractive for the manufacturer of chemicals that less product is used."

The Austrian experience with the model shows that it improves the quality of chemicals management at all stages. "This is because it requires accurate knowledge of all material flows in order to validate the profit sharing. In addition to the economically-driven ecological efficiency, chemical leasing is a technological driver that accelerates the time to market for products as well as technologies".

The challenge with chemical leasing is that it requires time and resources to implement. "Although we have managed to document dozens of showcases and develop templates and toolkits, the model has to be adapted to the specific circumstances. However, once established, it can lead to long-lasting, high-end business relationships," Dr Jakl explains.

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The Austrian government is currently looking at ways of speeding up the implementation of chemical leasing. "

We are, for example, integrating it into the eco-labelling criteria and exploring possibilities for benefits in authorisation schemes where a product's application is restricted to chemical leasing cases. From an economical and ecological point of view, I think chemical leasing should become the standard business model in the chemicals area," he concludes.

UNIDO DEFINITION OF CHEMICAL LEASING

- Chemical leasing is a service-oriented business model that shifts the focus from increasing the sales volume of chemicals, towards a value-added approach.
- The producer mainly sells the functions performed by the chemical, and functional units are the main basis for payment.
- Within chemical leasing business models, the responsibility of the producer and service provider is extended and may include the management of the entire life cycle.
- Chemical leasing strives for a win-win situation. It aims to increase the efficient use of chemicals while reducing the risks of chemicals, and protecting human health.

Today, the UNIDO initiative is supported by the governments of Austria, Germany and Switzerland.

The Global Chemical Leasing Award was launched in 2010 to enhance the visibility of chemical leasing worldwide and recognise best practice in chemical leasing. For the 2014 Award, applications were received from 20 countries.

Watch the video on chemical leasing online:
https://www.youtube.com/watch?v=3Vvcp4TGG0w#t=35

ECHA Helpdesk's top tips: How to change your company name or legal personality

TEXT BY ANCA-MIRELA PETRISOR

Is your company changing its name or its legal personality? This might mean splitting into separate entities, being merged or taken over. What happens with your REACH (pre-)registrations or CLP notifications? Here are some of the most common questions and related advice from the ECHA Helpdesk.

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ECHA Helpdesk reminds companies what to do if their name or legal personality changes.

Can I sell my registration, pre-registration or CLP notification to another company?

Registrations, pre-registrations and notifications under the REACH and CLP regulations cannot be traded. They can however be transferred in the same way as physical assets (such as production facilities or staff) when companies merge or split.

Here are two examples:

1. If a manufacturing plant splits from a mother company, becoming an independent legal entity, it can receive the registration of the substance it manufactures.
2. A corporation can buy a business unit from another company, like a warehouse responsible for the import of a mixture. When buying the warehouse, the CLP notification and pre-registrations made by the company in relation to the import can be transferred to the corporation along with the transfer of the warehouse.

How do I inform ECHA if my company name or legal personality has changed?

If your company name changes, you need to log into REACH-IT and update your company identifiers. However, if the legal personality of your company changes, you need to notify ECHA in REACH-IT through 'legal entity change'.

For company name changes, ECHA does not charge a fee. However, if your company is changing its legal personality, a fee may be applicable, depending on the type of assets transferred.

Changes of legal personality include:

- Mergers (absorptions, joining of equals);
- Company splits (spin-offs, demergers);
- Asset transfers;
- Changes of Only Representative.

Fees are based on the size of your company as declared in REACH-IT, so make sure that you keep this information up-to-date.

It is good to keep in mind that company and contract laws differ in each Member State. So, make sure you check the applicable laws if you plan to transfer or sell assets internationally during a legal personality change.

If you are an Only Representative of a non-EU based manufacturer, you need to create separate REACH-IT accounts for each non-EU based manufacturer you represent. Each account should reflect the size of your client, not your company.

I am a non-EU based manufacturer and would like to change my Only Representative. How do I make sure that my registrations are transferred?

If you decide to change your Only Representative, your previous representative needs to accept the transfer of asset(s) (pre-registrations, registration, notifications, etc.) to your new representative in REACH-IT. When you hire Only Representatives or consultants, you should remember to include clauses in your agreement on how to handle these situations.

Further information:

Helpdesks
http://echa.europa.eu/support/helpdesks/

Practical Guide 8: How to report changes in identity of legal entities:
http://echa.europa.eu/documents/10162/13643/pg_8_legal_entity_change_en.pdf

REACH-IT Industry User Manual: Part 02 - Sign-up and account management:
http://echa.europa.eu/documents/10162/13654/reachit_signup_acmngt_en.pdf

REACH-IT Industry User Manual: Part 17 – Legal entity change:
http://echa.europa.eu/documents/10162/13654/legal_entity_change_en.pdf

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

Guest column: Johanna Salomaa-Valkamo, Tukes

Belle Busybody raises awareness about chemicals

This spring, a new and fresh face was introduced in Finland: Belle Busybody. Belle vlogs on YouTube, tweets, maintains her own Facebook profile, and posts pictures on her own Instagram account. A multichannel sensation, Belle Busybody also appears at young people's events, drops into confirmation camps, barbeques with technical students, and chills out at festivals and beaches. Belle finds out about tattoos, eyelash and nail extensions – and watches moped lads perform an oil change. She voices her concern about chemicals in textiles and the risks involved in hair colouring.

Johanna Salomaa-Valkamo.

WHO ON EARTH IS BELLE BUSYBODY?

Belle Busybody is the public face of the Finnish Safety and Chemicals Agency's (Tukes) chemical-related communications year, which is aimed at young people. Following the theme for 2014, which focused on families with children, the focus has shifted to communicating with young people on the chemical risks in their environments. The aim of systematic communication on chemicals is to improve chemical safety by distributing reliable information and getting the related issues into public debate.

As young people are a very challenging target group, we wanted to take a fresh and genuinely new approach to this year's campaign. In Finland, authorities and public agencies are often viewed as Belle Busybodies, issuing pointless warnings and trying to spoil everyone's fun with unnecessary restrictions. Such an impression is held by young people in particular. This gave us the idea of making use of this image in our campaigning and using the sympathetic and cheerful Belle Busybody as our public face. We aimed to avoid any sense of pretending to be young, since media savvy youths would easily see through the falseness of such an approach.

As major consumers of chemicals in many respects, young people are an important target group. In particular, hair colours, cheap jewellery, cosmetics, false eye lashes, gel nails, tattoos and clothing were selected for the awareness raising campaign. Busy Belle is enthusiastic and concerned about many issues, but she always takes an informative and friendly approach. For advice, she turns to the expertise of the Market Surveillance of Chemicals unit at Tukes and points people to the right sources of information. A story-based approach is a key part of the Belle Busybody communications concept – she has a goddaughter and friends, she meets and talks to people, posts features online on all sorts of issues and builds her own persona through various communication channels. The key message of the campaign is 'think first' ,as we want to make young people aware of the risks associated with colouring hair, using make-up and other forms of 'dolling up', so that they can make informed choices. We also encourage young people to become familiar with hazard pictograms and user instructions.

Tukes has published the "Contact allergies – 5 facts and tips" brochure, which gives youths practical advice on how to minimise the risk of developing allergies.

POSITIVE FEEDBACK

Belle Busybody has been given a warm reception both in the field and in the media. In reality a Communications Officer at Tukes, Belle Busybody has given several interviews to various media, appeared on morning television, and her tips have been passed on through many websites and blogs. She has also cooperated with other public agencies and made guest appearances at seminars. She has received positive feedback from young people. Her most popular videos have been watched thousands of times and her most popular posts have numerous 'likes' and 'shares'.

Although Belle Busybody will retire from public life at the end of 2015, the aim is to use the materials from the information campaign in subsequent teaching and awareness raising activities. The website will stay live and will provide teachers and others with valuable support and teaching material.

In the autumn, while Belle Busybody is still on tour conveying her message to young people, a new theme year focusing on construction chemicals will be prepared by Tukes for kick off at the beginning of 2016.

Lots of easily understood information on chemical-related issues, chemical abbreviations and other important topics are listed on Belle Busybody's own website http://www.sussiunatkoon.fi ('Goodness gracious' in English).

Johanna Salomaa-Valkamo, Director of Communications, Finnish Safety and Chemicals Agency

Channels
youtube: Tukesin kukkahattutäti
https://twitter.com/sussiunatkoon
https://Instagram.com/sussiunatkoon
https://facebook.com/sussiunatkoon

Belle Busybody's introductory video (in English)
https://www.youtube.com/watch?v=fssb0axv6Y8